(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
9 January 2003 (09.01.2003)

PCT

(10) International Publication Number
WO 03/002020 A2

(51) International Patent Classification[7]: A61F

(21) International Application Number: PCT/IE02/00090

(22) International Filing Date: 27 June 2002 (27.06.2002)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

2001/0591	27 June 2001 (27.06.2001)	IE
60/301,820	2 July 2001 (02.07.2001)	US
60/312,791	17 August 2001 (17.08.2001)	US
2001/0772	20 August 2001 (20.08.2001)	IE
60/330,627	26 October 2001 (26.10.2001)	US
2001/0946	26 October 2001 (26.10.2001)	IE

(71) Applicant *(for all designated States except US)*: **SALVIAC LIMITED** [IE/IE]; 39-40 Upper Mount Street, Dublin 2 (IE).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **KEEGAN, Martin** [IE/IE]; 114 Seacrest, Shangort Road, Knocknacarra, Galway (IE). **MOLLOY, Shane** [IE/IE]; Kilroe, Corrandulla, County Galway (IE). **COLL, Siora** [IE/IE]; Ardsallaghmore, Roscommon Town, County Roscommon (IE). **HORAN, Steven** [IE/IE]; Carrick, The Pidgeons, Athlone, County Westmeath (IE). **CASEY, Brendan** [IE/IE]; 87 Ros Ard, Cappagh Road, Barna, Galway (IE).

(74) Agents: **O'BRIEN, John** et al.; John A. O'Brien & Associates, 3rd floor, Duncairn House, 14 Carysfort Avenue, Blackrock, County Dublin (IE).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZM, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *with declaration under Article 17(2)(a); without abstract; title not checked by the International Searching Authority*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

WO 03/002020 A2

(54) Title: A CATHETER

(57) Abstract:

"A Catheter"

Introduction

This invention relates to a catheter for delivery of a stent through a vasculature over a guidewire.

A stent is a medical device commonly used in the repair of aneurysms, as liners for vessels, or to provide mechanical support to prevent the collapse of stenosed or occluded vessels. Stents are typically delivered in a compressed state to a specific location inside the lumen of a vessel or other tubular structure, and then deployed at that location in the lumen to an expanded state. A stent has a diameter in its expanded state which is several times larger than the diameter of the stent in its compressed state. Stents are also frequently deployed in the treatment of atherosclerotic stenosis in blood vessels, especially after percutaneous transluminal coronary angioplasty (PTCA) procedures, to improve the results of the procedure and to reduce the likelihood of restenosis.

This invention is aimed at providing a catheter which facilitates both delivery and deployment of a stent.

Statements of Invention

According to the invention there is provided a delivery catheter comprising:–

a catheter shaft defining a reception space for a stent; and

an operating element extending through the catheter shaft for engagement with a stent in the reception space to facilitate deployment of the stent from within the reception space upon movement of the catheter shaft relative to the operating element from a delivery configuration to a deployment configuration;

along at least a portion of the length of the operating element, the cross-sectional area of the operating element being small relative to the cross-sectional area of the catheter shaft.

In a preferred case a guidewire opening is provided in the catheter shaft, the guidewire opening being located a substantial distance distally of a proximal end of the catheter for rapid exchange of the catheter over a guidewire.

The relatively small cross sectional area of the actuator enables the actuator to be moved relative to the catheter body to deploy a medical device without occluding the proximal guidewire opening. In this way, the delivery catheter of the invention enables rapid exchange over a guidewire during deployment of the medical device.

The rapid exchange arrangement of the delivery catheter enables a single clinician to advance the catheter over a guidewire and deploy a medical device, such as a stent at a desired treatment site in a vasculature.

In one embodiment of the invention the cross-sectional area of the operating element is small relative to the cross-sectional area of the catheter shaft in the region of the guidewire opening. Preferably in the delivery configuration the cross-sectional area of the operating element is small relative to the cross-sectional area of the catheter shaft for a distance of at least 10mm proximally of the guidewire opening. Most preferably in the delivery configuration the cross-sectional area of the operating element is small relative to the cross-sectional area of the catheter shaft for a distance

of at least 20mm proximally of the guidewire opening. Ideally in the delivery configuration the cross-sectional area of the operating element is small relative to the cross sectional area of the catheter shaft for a distance of at least 30mm proximally of the guidewire opening. Desirably in the delivery configuration the cross sectional area of the operating element is small relative to the cross-sectional area of the catheter shaft for a distance of at least 40mm proximally of the guidewire opening.

In another embodiment the cross sectional area of the operating element is in the range of from 0.008" to 0.015". Ideally the cross sectional area of the operating element is in the range of from 0.01" to 0.012".

The operating element enables a user to achieve good pushability for a steady, accurate deployment of a stent at a desired site in a vasculature while ensuring the overall crossing profile of the delivery catheter is kept to a minimum.

The operating element may comprise a control wire. In addition during advancement of the catheter through a vasculature, the control wire may bend around its own neutral axis. This results in the contribution of the control wire to the overall stiffness of the catheter being kept to a minimum for a highly trackable delivery catheter. Preferably the operating element comprises a push wire.

The operating element may comprise a coiled spring.

In another case the operating element is of a polymeric material.

The operating element may comprise a hypotube.

Preferably the operating element defines a lumen therethrough.

In a preferred embodiment of the invention the operating element comprises a proximal actuating element, and a distal engagement element for engaging a stent in the reception space. Ideally the engagement element comprises a pusher. The pusher may extend fully around the circumference of the engagement element. In one case the pusher comprises a coiled spring. The pusher may alternatively extend partially around the circumference of the engagement element.

Preferably the engagement element is attached to the actuating element. The engagement element may be integral with the actuating element. The operating element may be integral with the engagement element. This enables ease of manufacturing and minimises the catheter profile in the distal region of the catheter.

In a preferred case the engagement element extends distally of the actuating element.

The engagement element may define a guidewire lumen therethrough.

Most preferably the guidewire opening in the catheter shaft is moveable relative to the guidewire lumen of the engagement element upon deployment of a stent from within the reception space.

In one embodiment the catheter comprises a lateral support for the actuating element. The lateral support may be mounted to the catheter shaft. Ideally the lateral support comprises a tubular member through which the actuating element extends.

In a preferred embodiment the catheter comprises a platform on which a stent may be mounted in the reception space. The platform may comprise a tubular member. Preferably the tubular member defines a guidewire lumen therethrough. The tubular member may have a flushing opening in a wall of the tubular member.

The flushing lumen arrangement enables both the guidewire lumen and the reception space to be flushed by passing a flushing liquid into the catheter body at the proximal end or the distal end of the catheter body. This provides for a fast, efficient means of flushing the delivery catheter before use.

In one case the platform is attached to the operating element. Ideally the platform extends distally of the operating element.

In another embodiment of the invention the catheter comprises a tip distally of the platform. Preferably the tip is configured to define a smooth crossing profile from the tip to the catheter shaft. The tip may taper distally inwardly.

In a preferred embodiment the catheter shaft is slidably movable relative to the operating element. Ideally the catheter shaft is movable proximally relative to the operating element to deploy a stent from within the reception space.

The catheter shaft may comprise a proximal shaft portion and a distal pod, the pod defining the reception space. Preferably the proximal shaft portion is offset in the radial direction from the pod. Ideally the proximal shaft portion is of a smaller diameter than the pod. The pod may comprise means to radially reinforce the pod. The reinforcement around the reception space ensures that when the delivery catheter of the invention is used to deliver a self-expanding stent, the device is maintained in a low-profile collapsed configuration. In one case the reinforcement means comprises one or more reinforcement elements embedded in a wall of the pod. Preferably the reinforcement element is of a high hoop strength material. Ideally the reinforcement element is braided. The reinforcement element may comprise a coil.

In one embodiment the proximal shaft portion tapers distally inwardly. The proximal shaft portion may comprise a hypotube.

In another case the proximal shaft portion comprises means to radially reinforce the proximal shaft portion.

The catheter shaft may comprise a mounting piece for attaching the pod to the proximal shaft portion. Preferably the distal end of the proximal shaft portion is located distally of the proximal end of the pod. The mounting piece may be more flexible than the proximal shaft portion and the pod.

In another embodiment the mounting piece is more stiff than the proximal shaft portion and the pod.

The mounting piece may taper proximally inwardly. The mounting piece may taper distally inwardly.

In one case the guidewire opening in the catheter shaft is provided by an opening in the mounting piece.

Desirably the guidewire opening in the catheter shaft faces in a direction substantially parallel to the longitudinal axis of the catheter. Most preferably the guidewire opening faces proximally.

In a further preferred embodiment the catheter comprises means to guide passage of a guidewire through the guidewire opening in the catheter shaft.

The means to guide passage may comprise a guide tube through which a guidewire may pass. Preferably the guide tube extends at least partially internally through the catheter shaft.

The guide tube may extend at least partially externally of the catheter shaft. Ideally the guide tube is mounted to the catheter shaft.

In another case the means to guide passage comprises a guiding ramp.

In another aspect, the invention provides a catheter comprising a proximal shaft portion and a distal shaft portion attached to the proximal shaft portion, and means to stiffen the catheter at the junction between the proximal shaft portion and the distal shaft portion.

In one embodiment the catheter comprises a mounting piece for attaching the distal shaft portion to the proximal shaft portion. Preferably the distal end of the proximal shaft portion is located distally of the proximal end of the distal shaft portion to stiffen the junction. Ideally the mounting piece is more flexible than the proximal shaft portion and the distal shaft portion.

In another embodiment the mounting piece is more stiff than the proximal shaft portion and the distal shaft portion to stiffen the junction.

In one case the catheter comprises strain relief means. The mounting piece may taper distally inwardly. The mounting piece may taper proximally inwardly.

Preferably a guidewire opening is provided in the catheter, the guidewire opening being located a substantial distance distally of a proximal end of the catheter for rapid exchange of the catheter over a guidewire. The guidewire opening may be provided by an opening in the mounting piece. Ideally the guidewire opening faces in a direction substantially parallel to the longitudinal axis of the catheter.

The guidewire exits the guidewire lumen through the proximal guidewire opening in a substantially longitudinal direction parallel to the sheath and the catheter body. In this manner, the overall crossing profile of the delivery catheter is kept to a minimum.

In one case the catheter comprises means to guide passage of a guidewire through the guidewire opening in the catheter. The means to guide passage may be provided by the mounting piece.

According to a further aspect of the invention there is provided a delivery catheter comprising:-

a catheter shaft defining a reception space for a stent;

a guidewire opening being provided in the catheter shaft; and

an engagement element for engagement with a stent in the reception space to facilitate deployment of the stent from within the reception space upon movement of the catheter shaft relative to the engagement element;

the engagement element defining a guidewire lumen therethrough;

the guidewire opening in the catheter shaft being movable relative to the guidewire lumen of the engagement element upon deployment of a stent from within the reception space.

In one embodiment the guidewire opening in the catheter shaft is located a substantial distance distally of a proximal end of the catheter for rapid exchange of the catheter over a guidewire. Preferably the guidewire opening in the catheter shaft faces in a direction substantially parallel to the longitudinal axis of the catheter.

The catheter may comprise means to guide passage of a guidewire through the guidewire opening in the catheter shaft.

In one case the catheter comprises an operating element extending through the catheter shaft, the engagement element being provided by at least part of the operating element.

The catheter shaft may be slidably movable relative to the engagement element. Ideally the catheter shaft is movable proximally relative to the engagement element to deploy a stent from within the reception space.

The invention also provides in a further aspect a delivery catheter comprising:-

a catheter shaft defining a reception space for a stent; and

a control wire extending through a substantial portion of the length of the catheter shaft for engagement with a stent in the reception space to facilitate deployment of the stent from within the reception space upon movement of the catheter shaft relative to the operating element.

In one embodiment of the invention the catheter shaft defines a wire lumen extending from a proximal end of the catheter to the reception space, and the control wire extends through the full length of the wire lumen.

The control wire may be a push wire. Ideally the control wire comprises a coiled spring.

The catheter may comprise a lateral support for the control wire.

In one case the diameter of the wire is in the range of from 0.008" to 0.015". Ideally the diameter of the wire is in the range of from 0.01" to 0.012".

Brief Description of the Drawings

The invention will be more clearly understood from the following description of some embodiments thereof, given by way of example only, with reference to the accompanying drawings, in which:-

Fig. 1 is a partially cut-away, perspective view of a delivery catheter according to the invention passing over a guidewire;

Figs. 2 and 2(a) are partially cut-away, perspective views of the catheter of Fig. 1, in use;

Fig. 2(b) is an enlarged, partially cut-away, perspective view of a part of the catheter of Fig.1, in use;

Fig. 2(c) is a partially cross-sectional, side view of the part of Fig. 2(b);

Figs. 2(d) and 2(e) are views similar to Figs. 2(b) and 2(c) of the part in another position of use;

Figs. 2(f) and 2(g) are views similar to Figs. 2(b) and 2(c) of the part in a further position of use;

Fig. 3 is a perspective view of a proximal end of the catheter of Fig. 1;

Fig. 3(a) is a schematic view illustrating flushing of the catheter of Fig. 1;

Fig. 3(b) is a cross-sectional, side view illustrating flushing of the catheter of Fig. 1;

Figs. 3(c) to 3(e) are partially cross-sectional, side views of the catheter of Fig. 1, in use;

Figs. 3(f) to 3(h) are schematic views of the catheter of Fig. 1, in use;

Figs. 3(i) and 3(j) are cross-sectional, side views of the catheter of Fig. 1, in use;

Fig. 3(k) is an enlarged, partially cut-away, perspective view of a part of the catheter of Fig. 1, in use;

Fig. 3(m) is a partially cross-sectional, side view of the part of Fig. 3(k);

Figs. 3(n) and 3(p) are views similar to Figs. 3(k) and 3(m) of the part in another position of use;

Fig. 3(q) is a schematic view of the catheter of Fig. 1, in use;

Fig. 3(r) is a cross-sectional, side view of the catheter of Fig. 1, in use;

Fig. 3(s) is a schematic view of the catheter of Fig. 1, in use;

Fig. 3(t) is a schematic view illustrating flushing of the catheter of Fig. 1;

Fig. 3(u) is a cross-sectional, side view illustrating flushing of the catheter of Fig. 3(t);

Fig. 3(v) is a schematic view illustrating flushing of the catheter of Fig. 1;

Fig. 3(w) is a cross-sectional, side view illustrating flushing of the catheter of Fig. 3(v);

Fig. 3(x) is a schematic view illustrating flushing of the catheter of Fig. 1;

Fig. 3(y) is a cross-sectional, side view illustrating flushing of the catheter of Fig. 3(x);

Fig. 4 is a partially cut-away, perspective view of another delivery catheter according to the invention passing over a guidewire;

Fig. 5 is a cross-sectional, side view of the catheter of Fig. 4 passing over a guidewire;

Figs. 6 to 8 are partially cross-sectional, side views of the catheter of Fig. 4, in use;

Figs. 9 and 10 are cross-sectional, side views of a part of the catheter of Fig. 4;

Fig. 11 is a cross-sectional, side view of a part of another delivery catheter according to the invention;

Fig. 12 is a partially cut-away, perspective view of a part of a further delivery catheter according to the invention;

Fig. 13 is a cross-sectional, side view of the part of Fig. 12;

Figs. 13(a) to 13(c) are partially cut-away, perspective views of the part of Fig. 12, in use;

Figs. 14 to 16 are cross-sectional, side views of a part of other delivery catheters according to the invention;

Fig. 17 is a partially cut-away, perspective view of another delivery catheter according to the invention passing over a guidewire;

Fig. 18 is a cross-sectional, side view of the catheter of Fig. 17 passing over a guidewire;

Fig. 19(a) is a cross-sectional, side view of the catheter of Fig. 17, in use;

Fig. 19(b) is a side view of a part of the catheter of Fig. 17;

Figs. 19(c) and 19(d) are cross-sectional, side views of the catheter of Fig. 17, in use;

Fig. 20 is a side view of a part of another delivery catheter according to the invention;

Fig. 21 is a cross-sectional, side view of another delivery catheter according to the invention passing over a guidewire;

Figs. 22(a) to 24(b) are side views of a part of other delivery catheters according to the invention;

Fig. 25 is a perspective view of a part of a further delivery catheter according to the invention;

Fig. 26 is a side view of the part of Fig. 25 in place in the catheter;

Figs. 26(d) and 26(e) are perspective views of parts of another delivery catheter according to the invention;

Figs. 26(a) to 26(c) are cross-sectional, side views of another delivery catheter according to the invention, in use;

Fig. 27 is a cross-sectional, side view of a part of another delivery catheter according to the invention passing over a guidewire;

Figs. 28 to 30 are cross-sectional, side views of another delivery catheter according to the invention, in use; and

Figs. 31 and 32 are enlarged, partially cut-away, perspective views of a part of the catheter of Figs. 28 to 30, in use.

Detailed Description

Referring to the drawings there is illustrated a delivery catheter according to the invention. The delivery catheter is suitable for delivery of a self-expanding stent through a vasculature over a guidewire, and for deployment of the stent at a desired site in the vasculature. The delivery catheter is configured for rapid exchange over a guidewire during both delivery and deployment of the stent.

Figs. 1 to 3(y) illustrate a delivery catheter 1 according to the invention. The catheter 1 comprises a main catheter body 2, preferably a hypotube, a distal sheath 4, and an elongate actuator, in this case in the form of a push wire 3.

The sheath 4 defines an internal reception space for a medical device, such as a self-expanding stent 7, during delivery of the collapsed stent 7 to a desired treatment site in a vasculature. The stent 7 may, for example, be a self expanding stent of the type described in US 5,827,321. The diameter of the sheath 4 is sized to contact the stent 7 to retain the stent 7 in a collapsed configuration in the reception space during delivery to the desired treatment site.

The sheath 4 preferably comprises a reinforcement embedded into the sheath 4 to enhance the hoop strength of the sheath 4 to ensure the self-expanding stent 7 is maintained in a low-profile collapsed configuration during delivery of the stent 7 to the desired treatment site. In this case, the reinforcement is provided by a braid or coil of a high-strength material, such as stainless steel.

A suitable material for the sheath 4 is nylon, or PEBA, or polyamide, or polyurethane, or PEEK.

The catheter body 2 has a wire lumen extending through the full length of the catheter body 2, and the wire 3 extends through this wire lumen.

At the distal end of the wire 3, the catheter 1 comprises an abutment means for engagement with the stent 7 in the reception space. The abutment means is fixedly attached to the distal end of the wire 3.

The catheter 1 comprises a tubular inner core 5 extending through the sheath 4, and a coiled spring 6 mounted around the inner core 5. The inner core 5 extends through the full length of the coiled spring 6, which acts as an abutment means. The coiled spring 6 is formed integrally with the wire 3, and the coiled spring 6 extends over part of the inner core 5 with the distal end of the spring 6 spaced proximally of the distal end of the inner core 5.

The inner core 5 has a conical tip 8 at the distal end of the inner core 5, the tip 8 tapering distally inwardly. The tip 8 minimises the likelihood of snagging of the delivery catheter 1 during advancement of the catheter 1 through a vasculature. The arrow-head shape of the tip 8 also assist in centring the catheter 1 during advancement.

The tip 8 and the inner core 5 define a guidewire lumen therethrough.

A suitable material for the tip 8 is PEBA, or polyurethane, or silicone, or polyvinylchloride, or low density polyethylene.

During delivery of the stent 7 through a vasculature, the collapsed stent 7 is mounted around the inner core 5 distally of the coiled spring 6, and the distal end of the sheath 4 engages the proximal end of the tip 8 for a smooth crossing profile, as illustrated in Fig. 1.

Marker bands 13 are provided around the inner core 5 at the distal end of the coiled spring 6 and at the proximal end of the tip 8. The marker bands 13 enable the clinician to visualise the location of the collapsed stent 7.

A flushing opening 14 is provided in the inner core 5 at the distal end of the spring 6 in communication with the guidewire lumen (Fig. 2(a)).

The catheter body 2 is fixedly attached to the sheath 4 by means of a junction piece 9. Both the catheter body 2 and the sheath 4 are attached to the junction piece 9 by bonding using an adhesive.

As illustrated in Figs. 2(b) to 2(g), the junction piece 9 has a wire lumen therethrough aligned with the wire lumen of the catheter body 2 for passage of the wire 3 distally through the junction piece 9 to the coiled spring 6.

The junction piece 9 also has a guidewire lumen therethrough aligned with the guidewire lumen of the inner core 5 for passage of a guidewire 10 proximally from the inner core 5 (Figs. 2(b) and 2(c)), through the junction piece 9 (Figs. 2(d) and 2(e)), and out of the junction piece 9 through a proximal guidewire opening 11 (Figs. 2(f) and 2(g)).

A guide tube 12 extends distally from the junction piece 9 part of the distance towards the inner core 5. The guide tube 12 acts as a funnel to assist in guiding the guidewire 10 from the guidewire lumen of the inner core 5 towards the guidewire lumen of the junction piece 9, as illustrated in Figs. 2(d) and 2(e).

The longitudinal axis of the catheter body 2 is offset in the radial direction from the longitudinal axis of the sheath 4, and the catheter body 2 has a smaller diameter than the sheath 4. This arrangement provides for greater space at the proximal end of the junction piece 9 for the proximal guidewire opening 11. The guidewire 10 passes through the proximal guidewire opening 11 in a direction substantially parallel to the longitudinal axis of the delivery catheter 1, as illustrated in Figs. 2(f) and 2(g). This arrangement minimises the overall crossing profile of the catheter 1. In particular the profile is not increased due to the passage of the guidewire 10 through the proximal guidewire opening 11.

The distal end of the catheter body 2 is located distally of the proximal end of the sheath 4 such that there is an overlap d between the catheter body 2 and the sheath 4, as illustrated in Fig. 2(c). This arrangement stiffens the catheter 1 at the junction between the catheter body 2 and the sheath 4, and thus aids in a smooth transition of the retraction force from the catheter body 2 to the sheath 4. The stress exerted on the junction piece 9 is thus minimised. In addition, the possibility of kinking at the transition between the catheter body 2 and the sheath 4 is minimised due to the

flexural stiffness being maintained at a higher value than that of the adjoining sections.

Because the overlap d aids in kink prevention, the junction piece 9 may be formed of a material more flexible than the catheter body 2 and the sheath 4. This provides greater trackability to the catheter 1 in the region of the junction piece 9.

In an alternative arrangement the junction piece may be formed of a material more stiff than the catheter body 2 and the sheath 4. In this way the stiff junction piece 9 stiffens the catheter 1 at the junction piece between the catheter body 2 and the sheath 4, and thus minimises the possibility of kinking of the catheter 1 at the junction. An overlap between the catheter body 2 and the sheath 4 may or may not be provided in this case.

The junction piece 9 tapers proximally inwardly towards the catheter body 2 to provide a means of strain relief. The junction piece 9 could also be tapered distally towards the sheath 4 for strain relief.

The junction piece 9 is profiled to form a smooth transition from the profile of the sheath 4 to the profile of the catheter body 2.

A suitable material for the junction piece 9 is polypropylene, or ABS, or nylon, or PEBA, or polyurethane, or polyvinylchloride, or polyethylene.

Because the cross-sectional area of the actuator wire 3 is small relative to the overall cross-sectional area of the sheath 4, the wire 3 can move proximally relative to the catheter body 2 without occluding the proximal guidewire opening 11 or interfering in any way with the passage of the guidewire 10 therethrough.

It will be appreciated that any suitable means may be employed at the proximal end of the delivery catheter 1 for moving the catheter body 2 proximally relative to the push wire 3.

For example, the proximal end of the catheter body 2 may be connected to a handle 20 and a proximal end of the actuator wire 3 may be operably associated with a rotatable dial 21 on the handle 20. Rotation of the dial 21 relative to the handle 20 moves the catheter body 2 proximally relative to the wire 3 to facilitate deployment of the stent 7, as illustrated in Fig. 3. The rotating retraction action ensures a smooth deployment of the stent 7.

Markings 22, 23 may be provided on the catheter body 2 to indicate the distance moved by the catheter body 2. The markings 22, 23 also indicate to the user the distance to the proximal guidewire opening 11 at the junction piece 9. This is important as the delivery catheter 1 is being withdrawn from a guide catheter.

In use, the stent 7 is collapsed down and mounted around the inner core 5 distally of the coiled spring 6. The sheath 4 is then advanced until the distal end of the sheath 4 engages the proximal end of the tip 8. The stent 7 is thus restrained in the collapsed configuration within the reception space.

To flush the delivery catheter 1 of any air bubbles, a flushing fluid is introduced through the tip 8 into the guidewire lumen of the inner core 5 using a syringe 24, as illustrated in Figs. 3(a) and 3(b). The flushing fluid passes through the flushing opening 14 into the reception space to ensure that the collapsed stent 7 and the reception space are fully flushed. The flushing fluid also passes proximally through the guidewire lumen of the inner core 5, through the guidewire lumen of the junction piece 9, and out of the junction piece 9 through the proximal guidewire opening 11 to ensure that the inner core 5, the coiled spring 6, the guide tube 12, and the junction piece 9 are all fully flushed.

A guide catheter 25 is next inserted into the vascular system, for example, into the femoral artery at the groin, and advanced through the vascular system until a distal end of the guide catheter is proximally of the desired treatment site 26 in the vasculature 27. The desired site in the vasculature 26 is typically a stenosed region.

The guidewire 10 is inserted into the vasculature 27 through the guide catheter 25, and advanced through the vasculature 27 until the guidewire 10 crosses the desired treatment site 26 in the vasculature 27. The guidewire 10 preferably has a flexible, steerable tip for ease of crossing of the stenosed region.

The delivery catheter 1 with the collapsed stent 7 is then ready to be advanced over the guidewire 10 through the vasculature 27. The proximal end of the guidewire 10 is threaded through the tip 8 (Fig. 3(c)) and passed proximally through the guidewire lumen of the inner core 5, guided by the guide tube 12 towards the guidewire lumen of the junction piece 9 (Fig. 3(d)), passed through the guidewire lumen of the junction piece 9, and out of the junction piece 9 through the proximal guidewire opening 11 (Fig. 3(e)), as described previously with reference to Figs. 2(b) to 2(g).

The catheter 1 is then inserted into the guide catheter 25 (Fig. 3(f)), advanced through the guide catheter 25 over the guidewire 10 in a rapid exchange manner (Fig. 3(g)), and advanced through the vasculature 27 over the guidewire 10 in a rapid exchange manner until the collapsed stent 7 is located at a desired treatment site 26 in the vasculature 27 (Figs. 3(h) and 3(i)).

To deploy the stent 7 at the desired treatment site 26, the proximal end of the push wire 3 is held in a fixed position, and the catheter body 2 is retracted proximally over the push wire 3 by rotating the dial 21 on the handle 20 (Fig. 3(j)). In this way, the coiled spring 6 is held in a fixed position abutting the stent 7 as the sheath 4 is retracted proximally. As the stent 7 is uncovered by the proximal movement of the

sheath 4, the stent 7 self-expands outwardly to engage the wall of the vasculature (Fig. 3(j)).

During this deployment action, the catheter body 2, the junction piece 9 and the guide tube 12 all move proximally relative to the push wire 3, the inner core 5 and the coiled spring 6, as illustrated by comparing the location of the components of the catheter 1 in Figs. 3(k) and 3(m) with the location of the components in Figs. 3(n) and 3(p). Thus the distance between the guidewire lumen defined through the guide tube 12 and the guidewire lumen defined through the inner core 5 increases as the stent 7 is deployed, as illustrated in Figs. 1 and 2. The guidewire 10 is unsupported between the inner core 5 and the guide tube 12, and the push wire 3 is unsupported between the proximal end of the coiled spring 6 and the wire lumen of the junction piece 9.

During deployment of the stent 7, the outward radial force exerted by the collapsed stent 7 on the interior surface of the sheath 4 decreases gradually from a maximum when the sheath 4 extends over the full length of the stent 7 with the distal end of the sheath 4 engaging a proximal end of the tip 8, to a minimum when the stent 7 is fully uncovered. Accordingly the force required to retract the sheath 4 decreases from a maximum when the sheath 4 extends over the full length of the stent 7 to a minimum when the stent 7 is fully uncovered, and the compressive force on the push wire 3 also decreases from a maximum when the sheath 4 extends over the full length of the stent 7 to a minimum when the stent 7 is fully uncovered.

The dial 21 on the handle 20 is continued to be rotated and the catheter body 2 is continued to be retracted proximally over the push wire 3 until the stent 7 has been fully uncovered by the sheath 4, and the stent 7 has been fully deployed in the vasculature 27, as illustrated in Figs. 3(q) and 3(r). The delivery catheter 1 is withdrawn from the vasculature 27 through the guide catheter 25 over the guidewire 10 in a rapid exchange manner, as illustrated in Fig. 3(s).

During this deployment action the catheter body 2, the junction piece 9, and the sheath 4 move proximally relative to the push wire 3, the inner core 5, and the coiled spring 6. Because the push wire 3 has a relatively small cross-sectional area relative to the overall cross-sectional area of the catheter 1, the junction piece 9 can move proximally relative to the wire 3 without the proximal guidewire opening 11 being occluded or the passage of the guidewire 10 therethrough being interfered with in any way, as illustrated in Figs. 3(k) to 3(p).

In this manner, the deployment action does not obstruct or interfere with in any way the passage of the guidewire 10 through the proximal guidewire opening 11. Thus the delivery catheter 1 of the invention facilitates rapid exchange of the catheter 1 over the guidewire 10 during both delivery of the stent 7 and during deployment of the stent 7.

Also during this deployment action, the sheath 4 is retracted proximally over the inner core 5 and the coiled spring 6 in a sliding manner, as illustrated in Figs. 3(j) and 3(r). Deployment of the stent 7 using the delivery catheter 1 of the invention does not adversely effect the crossing profile of the catheter 1. In particular the deployment action does not result in bulging or accordioning of the sheath 4 outwardly.

The coiled spring 6 prevents proximal motion of the collapsed stent 7 during retraction of the sheath 4 for a steady, controlled, accurate deployment of the stent 7.

In the delivery catheter 1 the abutment means is operatively coupled to the actuator wire 3, and the abutment means is located substantially co-linear with the longitudinal axis of the sheath 4. In this way, the actuator wire 3 is aligned substantially along the longitudinal axis of the catheter body 2 and aligned substantially along the longitudinal axis of the sheath 4. Thus the contribution of the

actuator wire 3 to the overall lateral stiffness of the delivery catheter 1 is minimised. The actuator wire 3 therefore provides pushability for deployment of the stent 7 without adversely effecting the trackability of the catheter 1 for delivery of the catheter 1 through a vasculature.

By providing the elongate actuator in the form of the wire 3, this enables a small cross-sectional area to be used while ensuring sufficient push is available to deploy the stent 7. In addition the wire 3 can bend around its own neutral axis with the wire material distributed as close as possible to the wire neutral axis. This results in a highly trackable wire 3.

It will be appreciated that the delivery catheter 1 may alternatively be flushed of any air bubbles by introducing a flushing fluid through the proximal guidewire opening 11 into the guidewire lumen of the junction piece 9 using the syringe 24, as illustrated in Figs. 3(t) and 3(u). The flushing fluid passes distally through the guidewire lumen of the inner core 5 and out through the tip 8 to ensure that the junction piece 9, the guide tube 12, the coiled spring 6 and the inner core 5 are all fully flushed. The flushing fluid also passes through the flushing opening 14 into the reception space to ensure that the collapsed stent 7 and the reception space are fully flushed.

As a further alternative the delivery catheter 1 may be flushed of any air bubbles by introducing the flushing fluid through the handle 20 at the proximal end of the catheter body 2 into the wire lumen of the catheter body 2 using the syringe 24, as illustrated in Figs. 3(v) and 3(w). The flushing fluid passes distally through the wire lumen of the catheter body 2 around the wire 3, through the guidewire lumen of the inner core 5, and out through the tip 8 to ensure that the catheter body 2 and the inner core 5 are fully flushed. The flushing fluid also passes proximally through the guidewire lumen of the junction piece 9 and out through the proximal guidewire opening 11 to ensure that the junction piece 9 is fully flushed.

A stylet 28 may be inserted through the tip 8, through the guidewire lumen of the inner core 5, through the guidewire lumen of the junction piece 9, and out through the proximal guidewire opening 11. By flushing the catheter 1 through the proximal handle 20 with the stylet 28 in place, the flushing fluid is blocked from passing distally through the guidewire lumen of the inner core 5, or from passing proximally through the guidewire lumen of the junction piece 9, as illustrated in Figs. 3(x) and 3(y). Instead the flushing fluid passes distally around the spring 6 into the reception space to ensure that the collapsed stent 7 and the reception space are fully flushed.

It will further be appreciated that the stent 7 may alternatively be deployed by advancing the push wire 3 distally while holding the catheter body 2 in a fixed position, or indeed by any suitable movement of the catheter body 2 proximally relative to the push wire 3.

Referring now to Figs. 4 to 9, there is illustrated another delivery catheter 30 according to the invention, which is similar to the delivery catheter 1 of Figs. 1 to 3(y), and similar elements in Figs. 4 to 9 are assigned the same reference numerals.

In this case, the proximal end 31 of the sheath 4 overlaps the distal end 32 of the catheter body 2. The sheath 4 is attached to the catheter body 2 by means of the junction piece 9 to which both the sheath 4 and the catheter body 2 are attached by means of a press-fit arrangement.

It will be appreciated that the attachment may alternatively be provided by any other suitable means, such as by an adhesive, or by RF welding, or by soldering.

The guidewire 10 passes through a U-shaped channel 33 between the junction piece 9 and the proximal end 31 of the sheath 4 to the proximal guidewire opening 11. This enables a particularly low profile junction piece 9 to be used.

The actuator wire 3 is fixed to an abutment means for engagement with the stent 7 in the reception space. The abutment means is provided in this case, by a tubular abutment 34 mounted around the inner core 5. The abutment means engages the stent 7 within the reception space upon movement of the sheath 4 proximally relative to the wire 3, and in this way facilities deployment of the stent 7 from within the reception space.

The catheter 30 comprises a connector part 35 between the distal end of the push wire 3 and the proximal end of the tubular abutment 34. The connector part 35 has a guidewire lumen 36 therethrough angled to guide the guidewire 10 in a radial direction towards the proximal guidewire opening 11, through which the guidewire 10 passes in substantially the longitudinal direction.

In use, the delivery catheter 30 is advanced through a vasculature 37 over the guidewire 10 in a rapid-exchange manner until the collapsed stent 7 is located at a desired site 38 in the vasculature 37 (Fig. 6), in a manner similar to that described previously. During delivery the junction piece 9 is immediately proximally of the connector part 35, as illustrated in Figs. 5 and 6.

The stent 7 is deployed by moving the catheter body 2 and the sheath 4 proximally while maintaining the position of the push wire 3 fixed. This maintains the stent 7 at the desired site 38 in the vasculature 37 as the sheath 4 is retracted, thus enabling the self-expanding stent 7 to deploy radially outwardly into engagement with the wall of the vasculature 37 at the desired site 38 (Fig. 7).

The catheter body 2 and the sheath 4 are retracted proximally until the stent 7 is fully deployed in the vasculature 37 (Fig. 8).

As the stent 7 is deployed, the junction piece 9 moves proximally with the catheter body 2 and the sheath 4, and the connector part 35 maintains its position at the distal end of the wire 3, as illustrated in Figs. 7 and 8.

It will be appreciated that the stent 7 may alternatively be deployed by maintaining the position of the catheter body 2 and the sheath 4 fixed and by moving the push wire 3 distally to deploy the stent 7 out of the reception space.

It will further be appreciated that any suitable movement of the wire 3 distally relative to the catheter body 2 and the sheath 4 may be used to deploy the stent 7 provided that the clinician ensures that the stent 7 deploys at the desired site 38 in the vasculature 37.

As illustrated in Figs. 6 to 8, as the stent 7 is deployed the junction piece 9 moves proximally relative to the connector part 35. If the U-shaped channel 33 and the angled lumen 36 of the connector part become misaligned, this could hinder or prevent passage of the guidewire 10 through the proximal guidewire opening 11.

The longitudinal axis of the catheter body 2 is radially offset from the longitudinal axis of the sheath 4 by a distance δ, as illustrated in Fig. 9. By maximising this offset distance δ, this arrangement minimises the freedom of the connector part 35 to rotate relative to the junction piece 9 due to rotation of the wire 3 relative to the catheter body 2. In this way, the possibility of misalignment between the U-shaped channel 33 and the angled lumen 36 of the connector part 35 is minimised.

The radial offset configuration also provides more space for the proximal guidewire opening 11 at the proximal end of the junction piece 9.

A temporary alignment means, such as a removable plug 40 may be inserted during assembly through the channel 33 into the angled lumen 36 of the connector part 35 to prevent misalignment before use of the delivery catheter 30, as illustrated in Fig. 10.

Alternatively a protrusion 50 may be provided on the junction piece 9 for reception in a co-operating recess 51 in the connector part 35 to prevent misalignment of the U-shaped channel 33 and the angled lumen 36 of the connector part 35 before use of the delivery catheter, as illustrated in Fig. 11.

Referring to Figs. 12 to 13(c) there is illustrated another delivery catheter 60 according to the invention, which is similar to the delivery catheter 30 of Figs. 4 to 9, and similar elements in Figs. 12 to 13(c) are assigned the same reference numerals.

In this embodiment, a distal end face 61 of the junction piece 9 slopes proximally in a conical manner towards the U-shaped channel 33. This conical sloping arrangement assist in guiding the guidewire 10 towards the channel 33, as illustrated in Figs. 13(a) to 13(c), thus minimising the possibility of misalignment occurring between the angled lumen 36 of the connector part 35 and the U-shaped channel 33.

It will be appreciated that the sloping distal end face 61 may be used to guide the guidewire 10 through the proximal guidewire opening 11 for a variety of alternative delivery catheters of the invention. In particular it is not essential that the delivery catheter includes the connector part 35.

An alignment means, such as the plug 40 as described previously with reference to Fig. 10, may be used to prevent misalignment of the U-shaped channel 33 and the angled lumen 36 of the connector part 35 before use of the catheter 70.

In Fig. 14, there is illustrated another delivery catheter 70 according to the invention, which is similar to the delivery catheter 30 of Figs. 4 to 9, and similar elements in Fig. 14 are assigned the same reference numerals.

The catheter 70 comprises a lateral support for the actuator wire 3. The support is provided, in this case, by a tubular member 71 mounted to the connector part 35 and extending proximally co-axially around the wire 3.

The tubular support 71 prevents buckling of the push wire 3 as the catheter body 2 and the sheath 4 are moved proximally relative to the wire 3 upon deployment of the stent 7.

It will be appreciated that the tubular member 71 may alternatively be mounted to the catheter body 2 or the sheath 4 or any other suitable mounting point.

Fig. 15 illustrates a further delivery catheter 80 according to the invention, which is similar to the delivery catheter 30 of Figs. 4 to 9, and similar elements in Fig. 15 are assigned the same reference numerals.

In this case, the actuator is provided in the form of a spring 81, and the catheter body 2 is provided in the form of a braided sheath. The junction piece 82 between the catheter body 2 and the sheath 4 is in the form of a strain relief transition piece.

One or more flushing lumena 90 may be provided through the connector part 35 as illustrated in Fig. 16. The flushing lumena 90 enable a flushing liquid to be passed distally through the actuator lumen in the catheter body 2, through the lumena 90, into the guidewire lumen 36 of the connector port 35, into the guidewire lumen of the inner core 5, and also into the reception space around the stent 7.

In this manner, the clinician can thoroughly flush both the reception space and the various guidewire lumena of the delivery catheter by passing a flushing liquid into the catheter body 2 from the proximal end of the catheter body 2, in a manner similar to that described previously with reference to Figs. 3(v) to 3(y).

It will be appreciated that the flushing fluid may alternatively be passed through a lumen in the actuator to the connector part 35. This may be a particularly suitable option when the actuator comprises a coiled spring 81.

It will further be appreciated that at least one flushing lumen may be provided through any suitable component of any of the delivery catheters of the invention, as described previously with reference to Figs. 1 to 15, to facilitate flushing of the guidewire lumen by passing a flushing fluid into the proximal end of the delivery catheter. For example flushing lumena may be provided in a tubular abutment, and/or an inner core, and/or a junction piece, and/or a guide connector part.

Figs. 17 to 19(d) illustrate another delivery catheter 100 according to the invention, which is similar to the delivery catheter 30 of Figs. 4 to 9, and similar elements in Figs. 17 to 19(d) are assigned the same reference numerals.

In this case, the tubular abutment 34 is directly fixed to the distal end of the actuator wire 3. The tubular abutment 34 is mounted to the inner core 5 with a partial overlap, such that the inner core 5 extends distally of the tubular abutment 34, and the tubular abutment 34 extends proximally of the inner core 5 (Fig. 18).

The catheter comprises a guide to guide passage of the guidewire 10 through the proximal guidewire opening 11, in this case, a guide tube 101 which extends co-axially within the tubular abutment 34, as illustrated in Fig. 18. The guide tube 101 is mounted at the proximal guidewire opening 11 at the junction piece 9 fixed between the sheath 4 and the catheter body 2.

During delivery of the stent 7 to the desired site 38 in the vasculature 37, a distal end of the guide tube 101 is located immediately proximally of a proximal end of the inner core 5, as illustrated in Figs. 19(a) and 19(b), to minimise the possibility of snagging of the guidewire 10 as the delivery catheter 100 advances over the guidewire 10.

As the stent 7 is deployed, the guide tube 101 moves proximally with the catheter body 2 and the sheath 4 in a telescoping manner through the tubular abutment 34 away from the inner core 5, as illustrated in Figs. 19(c) and 19(d).

The guidewire 18 passes out of the guide tube 101 through the proximal guidewire opening 11 substantially in the longitudinal direction (Fig. 18).

It will be appreciated that the guide tube 101 may alternatively or additionally extend proximally externally of the sheath 4.

The guide tube 101 may be mounted to the catheter body 2 or to the sheath 4.

The guide tube 101 is also suitable for use in a catheter in which the abutment means is in the form of a coiled spring 6, as illustrated in Fig. 20.

In Fig. 21 there is illustrated another delivery catheter 110 according to the invention, which is similar to the delivery catheter 100 of Figs. 17 to 20, and similar elements in Fig. 21 are assigned the same reference numerals.

In this case, the actuator comprises a close coiled spring 103. A proximal portion of the spring 103 is coiled and a distal portion 102 of the spring 103 to which the tubular abutment 34 is attached is uncoiled.

The spring actuator 103 enhances the trackability of the delivery catheter 110 during advancement of the catheter 110 through the vasculature 37.

As illustrated in Figs. 22(a) and 22(b), the spring actuator 103 may be integrally formed with the coiled spring abutment 6, as described previously with reference to Figs. 1 and 2. This arrangement results in a more secure connection between the actuator 103 and the abutment 6.

The spring 103 may be wound in the opposite direction to the spring 6 (Fig. 22(a)), or may be wound in the same direction as the spring 6 (Fig. 22(b)).

The springs 103, 6 may be formed from one coiled wire or from more than one coiled wire, as illustrated in Figs. 23(a) and 23(b). The properties of a spring formed from more than one coiled wire may be altered to suit the application of the coiled spring.

Again the springs 103, 6 may be wound in opposite directions (Fig. 23(a)), or in the same direction (Fig. 23(b)).

The actuator 120 may alternatively be at least partially of a suitable polymeric material, with the coiled spring abutment 6 mounted to the distal end of the actuator 120, as illustrated in Fig. 24(a), for example by welding, or soldering, or using an adhesive.

A heatshrink tubing 25 may be applied to the external surface of the coiled spring abutment 6, as illustrated in Fig. 24(b), to reduce the frictional resistance to relative movement between the spring 6 and the sheath 4 during deployment of the stent 7. Additionally or alternatively the spring 6 may be coated in polytetrafluoroethylene to reduce frictional forces.

The actuator may alternatively be at least partially of a hypotube material. Figs. 25 and 26 illustrate an embodiment in which the actuator comprises a proximal coiled spring portion 130 and a distal hypotube portion 131 to which the coiled spring abutment 6 is fixed. A slot 132 is provided in the hypotube portion 131 to accommodate extension of the guide tube 101 passed the hypotube portion 131 in a low-profile manner.

It will be understood that the abutment means may extend around only part of the circumference. For example, the abutment means may be provided in the form of a half-tube 350 fixedly attached to the distal end of the elongate actuator 351, as illustrated in Figs. 26(d) and 26(e). The half-tube 350 may be formed of a polymeric material or of a hypotube material or of any other suitable material.

Referring to Figs 26(a) to 26(c) there is illustrated another delivery catheter 200 according to the invention, which is similar to the delivery catheter 1 of Figs. 1 to 3(y), and similar elements in Figs. 26(a) to 26(c) are assigned the same reference numerals.

In this case the inner core 5 extends proximally a substantial distance such that during delivery of the collapsed stent 7 through the vasculature 27, the proximal end of the inner core 5 abuts the junction piece 9 (Fig. 26(a)).

In this way the inner core 5 assists in guiding passage of the guidewire 10 from the guidewire lumen of the inner core 5 through the guidewire lumen of the junction piece 9 and out through the proximal guidewire opening 11. In particular no guide means, such as a sloping end face, is required on the junction piece 9.

During deployment of the stent 7, the junction piece 9 moves proximally while the inner core 5 remains in a fixed position, as illustrated in Figs. 26(b) and 26(c). Thus the distance between the guidewire lumen of the inner core 5 and the guidewire

lumen through the junction piece 9 increases from a minimum during delivery of the stent 7 (Fig. 26(a)) to a maximum when the stent 7 is fully deployed (Fig. 26(c)).

In Fig. 27 there is illustrated a further delivery catheter 140 according to the invention, which is similar to the delivery catheter 200 of Figs. 26(a) to 26(c), and similar elements in Fig. 27 are assigned the same reference numerals.

In this case, the actuator wire 3 is fixed directly to the inner core 5 which extends proximally to the proximal guidewire opening 11.

The abutment means is provided by the distal end 141 of the wire 3, which directly engages the stent 7 in the reception space to facilitate deployment of the stent 7, upon movement of the catheter body 2 and the sheath 4 proximally relative to the wire 3.

In another case, a protrusion may be provided on the inner core 5 to engage the stent 7 in the reception space for deployment of the stent 7.

Referring to Figs. 28 to 32 there is illustrated another delivery catheter 300 according to the invention, which is similar to the delivery catheter 1 of Figs. 1 to 3(y), and similar elements in Figs. 28 to 32 are assigned the same reference numerals.

The catheter 300 is configured to be exchanged over the guidewire 10 in an over-the-wire manner. The catheter body 2 defines a guidewire lumen 301 extending from the proximal handle 20 to the reception space of the sheath 4. The guidewire 10 exits the guidewire lumen 301 through an opening in the handle 20 at the proximal end of the catheter 300 externally of the vasculature 27.

In use the catheter body 2 and the sheath 4 are moved proximally relative to the wire 3 to facilitate deployment of the stent 7 from within the reception space.

The invention is not limited to the embodiments hereinbefore described, with reference to the accompanying drawings, which may be varied in construction and detail.

5

CLAIMS

1. A delivery catheter comprising:-

a catheter shaft defining a reception space for a stent; and

an operating element extending through the catheter shaft for engagement with a stent in the reception space to facilitate deployment of the stent from within the reception space upon movement of the catheter shaft relative to the operating element from a delivery configuration to a deployment configuration;

along at least a portion of the length of the operating element, the cross-sectional area of the operating element being small relative to the cross-sectional area of the catheter shaft.

2. A catheter as claimed in claim 1 wherein a guidewire opening is provided in the catheter shaft, the guidewire opening being located a substantial distance distally of a proximal end of the catheter for rapid exchange of the catheter over a guidewire.

3. A catheter as claimed in claim 2 wherein the cross-sectional area of the operating element is small relative to the cross-sectional area of the catheter shaft in the region of the guidewire opening.

4. A catheter as claimed in claim 3 where in the delivery configuration the cross-sectional area of the operating element is small relative to the cross-sectional area of the catheter shaft for a distance of at least 10mm proximally of the guidewire opening.

5. A catheter as claimed in claim 4 wherein in the delivery configuration the cross-sectional area of the operating element is small relative to the cross-sectional area of the catheter shaft for a distance of at least 20mm proximally of the guidewire opening.

6. A catheter as claimed in claim 5 wherein in the delivery configuration the cross-sectional area of the operating element is small relative to the cross sectional area of the catheter shaft for a distance of at least 30mm proximally of the guidewire opening.

7. A catheter as claimed in claim 6 wherein in the delivery configuration the cross sectional area of the operating element is small relative to the cross-sectional area of the catheter shaft for a distance of at least 40mm proximally of the guidewire opening.

8. A catheter as claimed in any of claims 1 to 7 wherein the diameter of the operating element is in the range of from 0.008" to 0.015".

9. A catheter as claimed in claim 8 wherein the diameter of the operating element is in the range of from 0.01" to 0.012".

10. A catheter as claimed in any of claims 1 to 9 wherein the operating element comprises a control wire.

11. A catheter as claimed in claim 10 wherein the operating element comprises a push wire.

12. A catheter as claimed in any of claims 1 to 11 wherein the operating element comprises a coiled spring.

13. A catheter as claimed in any of claims 1 to 12 wherein the operating element is of a polymeric material.

14. A catheter as claimed in any of claims 1 to 13 wherein the operating element comprises a hypotube.

15. A catheter as claimed in any of claims 1 to 14 wherein the operating element defines a lumen therethrough.

16. A catheter as claimed in any of claims 1 to 15 wherein the operating element comprises a proximal actuating element, and a distal engagement element for engaging a stent in the reception space.

17. A catheter as claimed in claim 16 wherein the engagment element comprises a pusher.

18. A catheter as claimed in claim 17 wherein the pusher extends fully around the circumference of the engagement element.

19. A catheter as claimed in claim 18 wherein the pusher comprises a coiled spring.

20. A catheter as claimed in claim 17 wherein the pusher extends partially around the circumference of the engagement element.

21. A catheter as claimed in any of claims 16 to 20 wherein the engagement element is attached to the actuating element.

22. A catheter as claimed in claim 21 wherein the engagement element is integral with the actuating element.

23. A catheter as claimed in any of claims 16 to 22 wherein the engagement element extends distally of the actuating element.

24. A catheter as claimed in any of claims 16 to 23 wherein the engagement element defines a guidewire lumen therethrough.

25. A catheter as claimed in claim 24 wherein the guidewire opening in the catheter shaft is moveable relative to the guidewire lumen of the engagement element upon deployment of a stent from within the reception space.

26 A catheter as claimed in any of claims 16 to 25 wherein the catheter comprises a lateral support for the actuating element.

27. A catheter as claimed in claim 26 wherein the lateral support is mounted to the catheter shaft.

28 A catheter as claimed in claim 26 or 27 wherein the lateral support comprises a tubular member through which the actuating element extends.

29. A catheter as claimed in any of claims 1 to 28 wherein the catheter comprises a platform on which a stent may be mounted in the reception space.

30. A catheter as claimed in claim 29 wherein the platform comprises a tubular member.

31. A catheter as claimed in claim 30 wherein the tubular member defines a guidewire lumen therethrough.

32. A catheter as claimed in claim 30 or 31 wherein the tubular member has a flushing opening in a wall of the tubular member.

33. A catheter as claimed in any of claims 29 to 32 wherein the platform is attached to the operating element.

34. A catheter as claimed in any of claims 29 to 33 wherein the platform extends distally of the operating element.

35. A catheter as claimed in any of claims 29 to 34 wherein the catheter comprises a tip distally of the platform.

36. A catheter as claimed in claim 35 wherein the tip is configured to define a smooth crossing profile from the tip to the catheter shaft.

37. A catheter as claimed in claim 36 wherein the tip tapers distally inwardly.

38. A catheter as claimed in any of claims 1 to 37 wherein the catheter shaft is slidably movable relative to the operating element.

39. A catheter as claimed in any of claims 1 to 38 wherein the catheter shaft is movable proximally relative to the operating element to deploy a stent from within the reception space.

40. A catheter as claimed in any of claims 1 to 39 wherein the catheter shaft comprises a proximal shaft portion and a distal pod, the pod defining the reception space.

41. A catheter as claimed in claim 40 wherein the proximal shaft portion is offset in the radial direction from the pod.

42. A catheter as claimed in claim 41 wherein the proximal shaft portion is of a smaller diameter than the pod.

43. A catheter as claimed in any of claims 40 to 42 wherein the pod comprises means to radially reinforce the pod.

44. A catheter as claimed in claim 43 wherein the reinforcement means comprises one or more reinforcement elements embedded in a wall of the pod.

45. A catheter as claimed in claim 44 wherein the reinforcement element is of a high hoop strength material.

46. A catheter as claimed in claim 44 or 45 wherein the reinforcement element is braided.

47. A catheter as claimed in any of claims 44 to 46 wherein the reinforcement element comprises a coil.

48. A catheter as claimed in any of claims 40 to 47 wherein the proximal shaft portion tapers distally inwardly.

49. A catheter as claimed in any of claims 40 to 48 wherein the proximal shaft portion comprises a hypotube.

50. A catheter as claimed in any of claims 40 to 49 wherein the proximal shaft portion comprises means to radially reinforce the proximal shaft portion.

51. A catheter as claimed in any of claims 40 to 50 wherein the catheter shaft comprises a mounting piece for attaching the pod to the proximal shaft portion.

52. A catheter as claimed in any of claims 40 to 51 wherein the distal end of the proximal shaft portion is located distally of the proximal end of the pod.

53. A catheter as claimed in claim 52 wherein the mounting piece is more flexible than the proximal shaft portion and the pod.

54. A catheter as claimed in claim 51 or 52 wherein the mounting piece is more stiff than the proximal shaft portion and the pod.

55. A catheter as claimed in any of claims 51 to 54 wherein the mounting piece tapers proximally inwardly.

56. A catheter as claimed in any of claims 51 to 55 wherein the mounting piece tapers distally inwardly.

57. A catheter as claimed in any of claims 51 to 56 wherein the guidewire opening in the catheter shaft is provided by an opening in the mounting piece.

58. A catheter as claimed in any of claims 2 to 57 wherein the guidewire opening in the catheter shaft faces in a direction substantially parallel to the longitudinal axis of the catheter.

59. A catheter as claimed in claim 58 wherein the guidewire opening faces proximally.

60. A catheter as claimed in any of claims 2 to 59 wherein the catheter comprises means to guide passage of a guidewire through the guidewire opening in the catheter shaft.

61. A catheter as claimed in claim 60 wherein the means to guide passage comprises a guide tube through which a guidewire may pass.

62. A catheter as claimed in claim 61 wherein the guide tube extends at least partially internally through the catheter shaft.

63. A catheter as claimed in claim 61 or 62 wherein the guide tube extends at least partially externally of the catheter shaft.

64. A catheter as claimed in any of claims 61 to 63 wherein the guide tube is mounted to the catheter shaft.

65. A catheter as claimed in any of claims 60 to 64 wherein the means to guide passage comprises a guiding ramp.

66. A catheter comprising a proximal shaft portion and a distal shaft portion attached to the proximal shaft portion, and means to stiffen the catheter at the junction between the proximal shaft portion and the distal shaft portion.

67. A catheter as claimed in claim 66 wherein the catheter comprises a mounting piece for attaching the distal shaft portion to the proximal shaft portion.

68. A catheter as claimed in claim 66 or 67 wherein the distal end of the proximal shaft portion is located distally of the proximal end of the distal shaft portion to stiffen the junction.

69. A catheter as claimed in claim 68 wherein the mounting piece is more flexible than the proximal shaft portion and the distal shaft portion.

70. A catheter as claimed in claim 67 or 68 wherein the mounting piece is more stiff than the proximal shaft portion and the distal shaft portion to stiffen the junction.

71. A catheter as claimed in any of claims 66 to 70 wherein the catheter comprises strain relief means.

72. A catheter as claimed in claim 71 wherein the mounting piece tapers distally inwardly.

73. A catheter as claimed in claim 71 or 72 wherein the mounting piece tapers proximally inwardly.

74. A catheter as claimed in any of claims 66 to 73 wherein a guidewire opening is provided in the catheter, the guidewire opening being located a substantial distance distally of a proximal end of the catheter for rapid exchange of the catheter over a guidewire.

75. A catheter as claimed in claim 74 wherein the guidewire opening is provided by an opening in the mounting piece.

76. A catheter as claimed in claim 74 or 75 wherein the guidewire opening faces in a direction substantially parallel to the longitudinal axis of the catheter.

77. A catheter as claimed in any of claims 74 to 76 wherein the catheter comprises means to guide passage of a guidewire through the guidewire opening in the catheter.

78. A catheter as claimed in claim 77 wherein the means to guide passage is provided by the mounting piece.

79. A delivery catheter comprising:-

a catheter shaft defining a reception space for a stent;

a guidewire opening being provided in the catheter shaft; and

an engagement element for engagement with a stent in the reception space to facilitate deployment of the stent from within the reception space upon movement of the catheter shaft relative to the engagement element;

the engagement element defining a guidewire lumen therethrough;

the guidewire opening in the catheter shaft being movable relative to the guidewire lumen of the engagement element upon deployment of a stent from within the reception space.

80. A catheter as claimed in claim 79 wherein the guidewire opening in the catheter shaft is located a substantial distance distally of a proximal end of the catheter for rapid exchange of the catheter over a guidewire.

81. A catheter as claimed in claim 80 wherein the guidewire opening in the catheter shaft faces in a direction substantially parallel to the longitudinal axis of the catheter.

82. A catheter as claimed in any of claims 79 to 81 wherein the catheter comprises means to guide passage of a guidewire through the guidewire opening in the catheter shaft.

83. A catheter as claimed in any of claims 79 to 82 wherein the catheter comprises an operating element extending through the catheter shaft, the engagement element being provided by at least part of the operating element.

84. A catheter as claimed in any of claims 79 to 83 wherein the catheter shaft is slidably movable relative to the engagement element.

85. A catheter as claimed in any of claims 79 to 84 wherein the catheter shaft is movable proximally relative to the engagement element to deploy a stent from within the reception space.

86. A delivery catheter comprising:-

a catheter shaft defining a reception space for a stent; and

a control wire extending through a substantial portion of the length of the catheter shaft for engagement with a stent in the reception space to facilitate deployment of the stent from within the reception space upon movement of the catheter shaft relative to the operating element.

87. A catheter as claimed in claim 86 wherein the catheter shaft defines a wire lumen extending from a proximal end of the catheter to the reception space, and the control wire extends through the full length of the wire lumen.

88. A catheter as claimed in claim 86 or 87 wherein the control wire is a push wire.

89. A catheter as claimed in any of claims 86 to 88 wherein the control wire comprises a coiled spring.

90. A catheter as claimed in any of claims 86 to 89 wherein the catheter comprises a lateral support for the control wire.

91. A catheter as claimed in any of claims 86 to 90 wherein the diameter of the wire is in the range of from 0.008" to 0.015".

92. A catheter as claimed in claim 91 wherein the diameter of the wire is in the range of from 0.01" to 0.012".

93. A catheter substantially as hereinbefore described with reference to the accompanying drawings.

Fig. 2

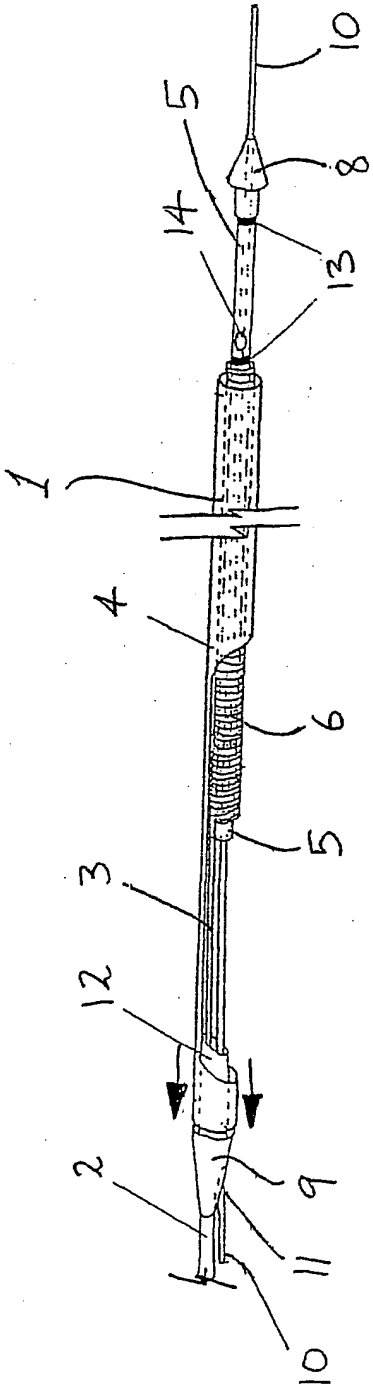
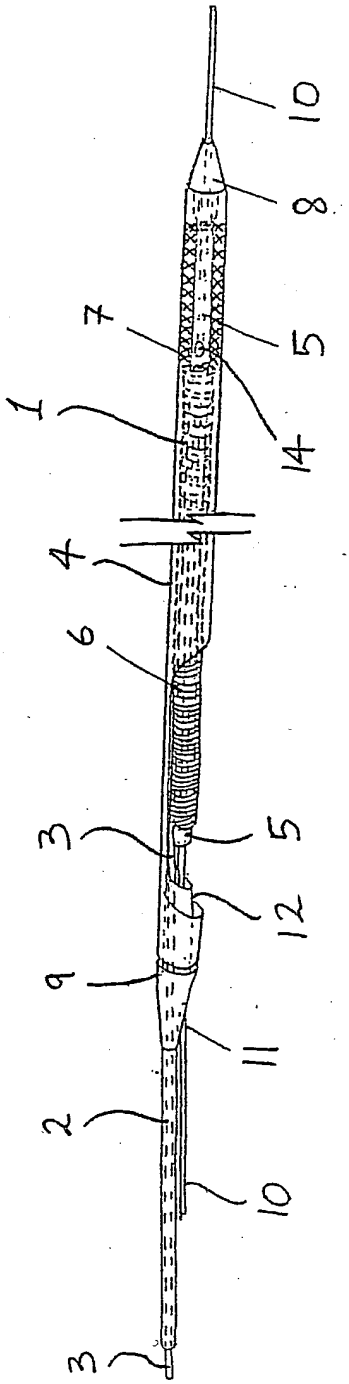
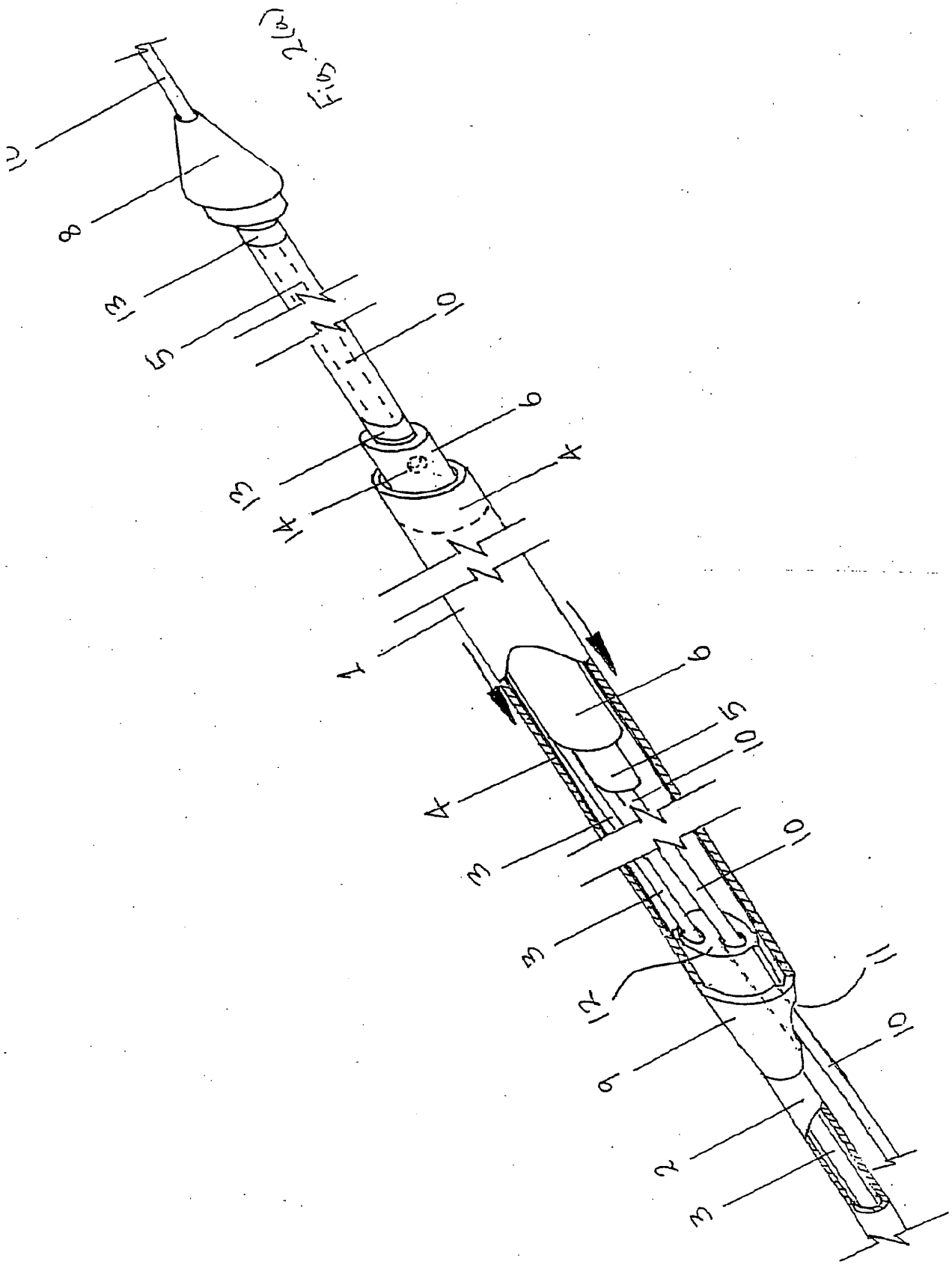


Fig. 1





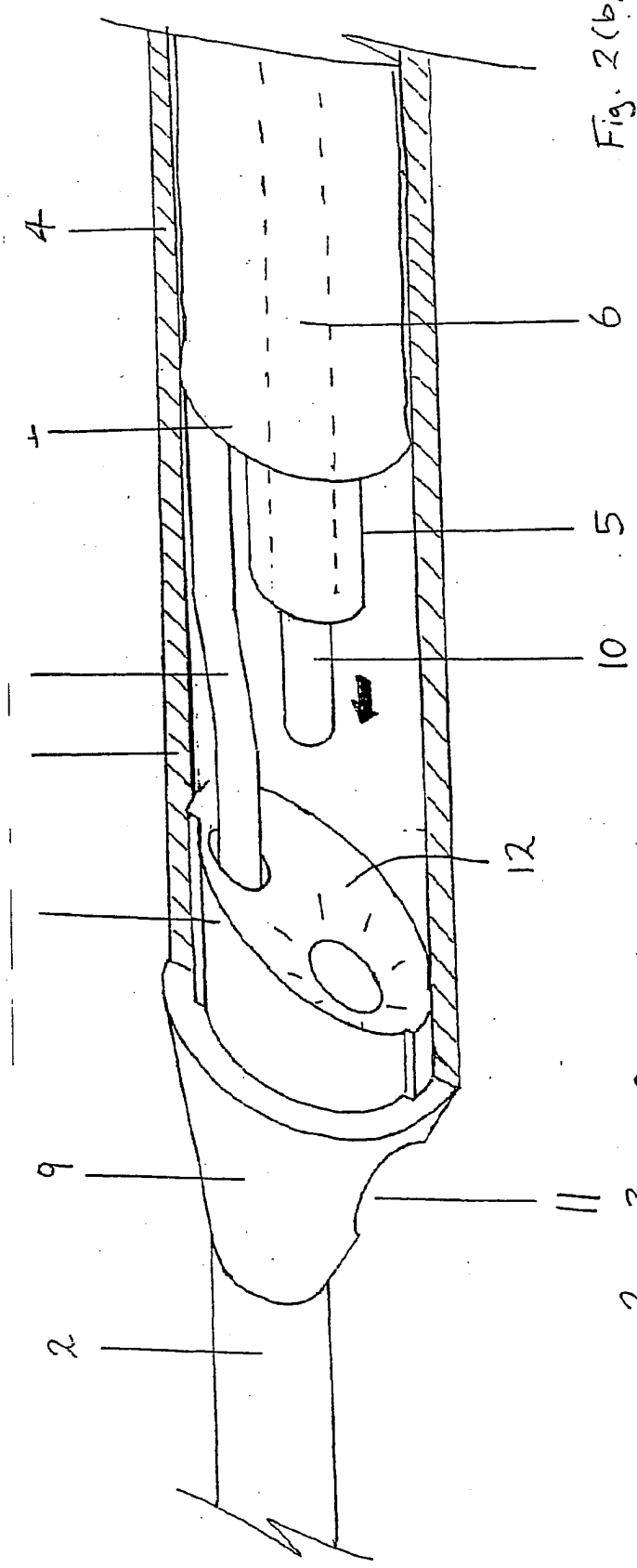


Fig. 2(b)

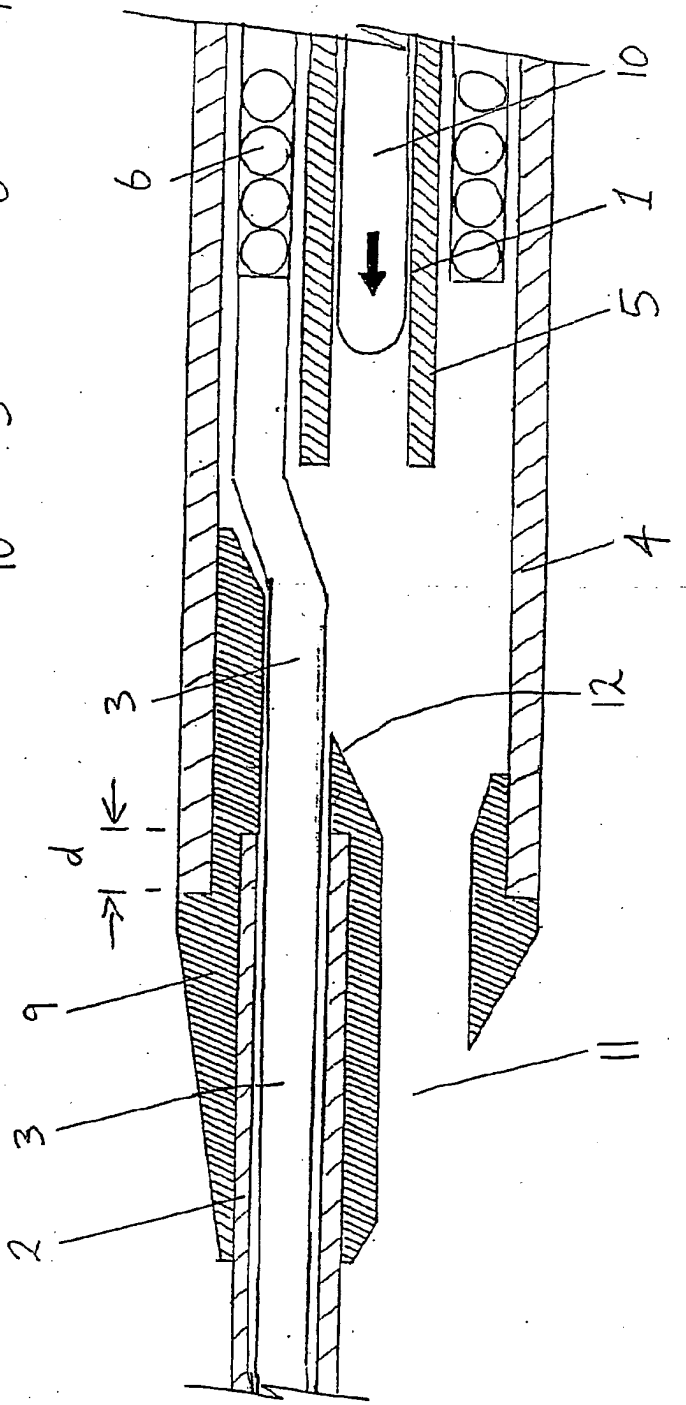


Fig. 2(c)

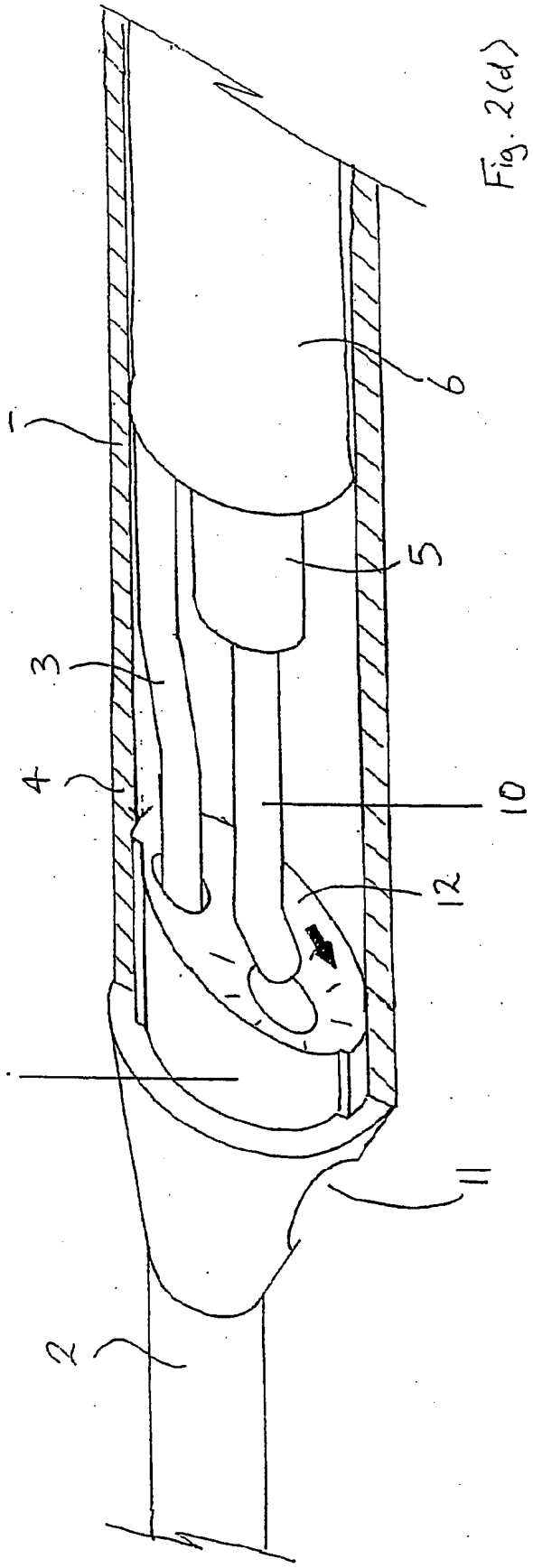


Fig. 2(d)

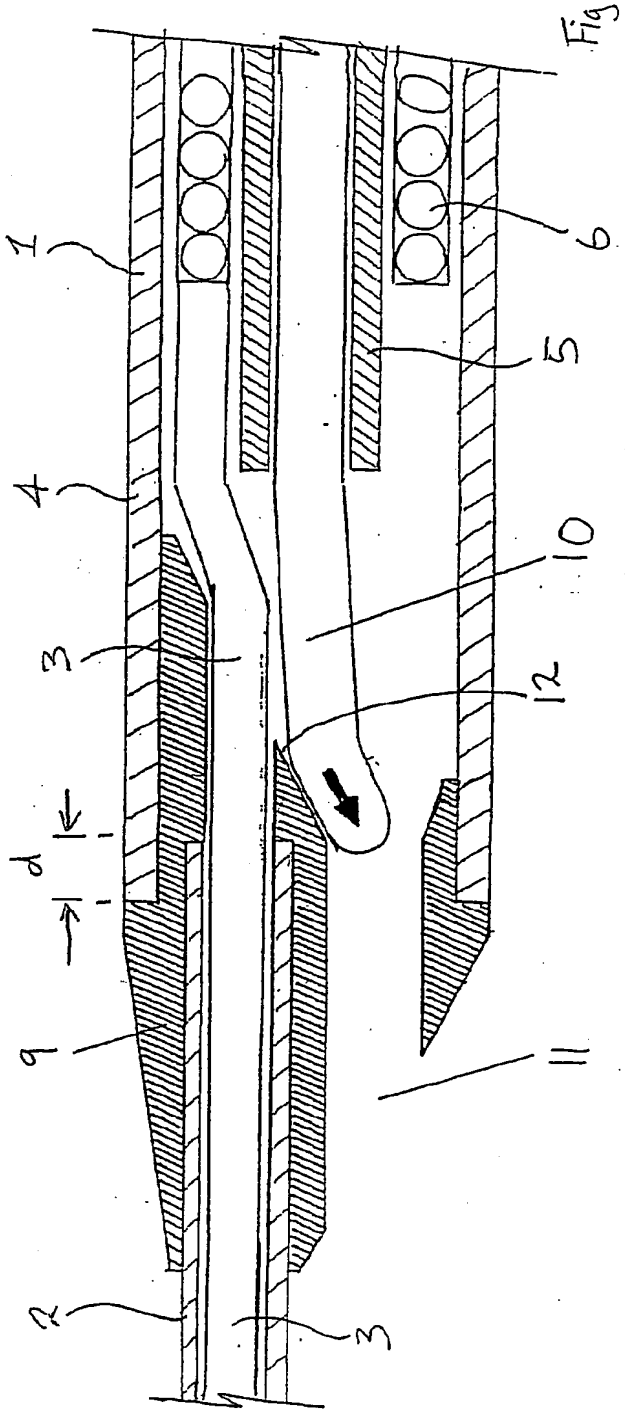


Fig. 2(e)

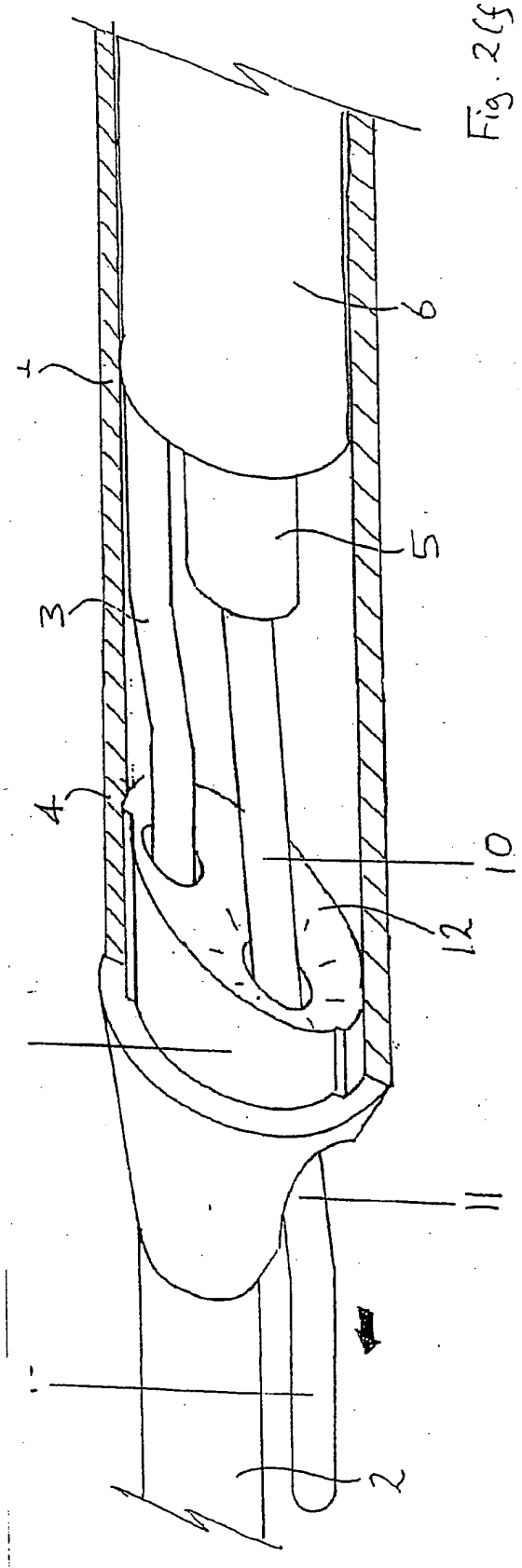


Fig. 2(f)

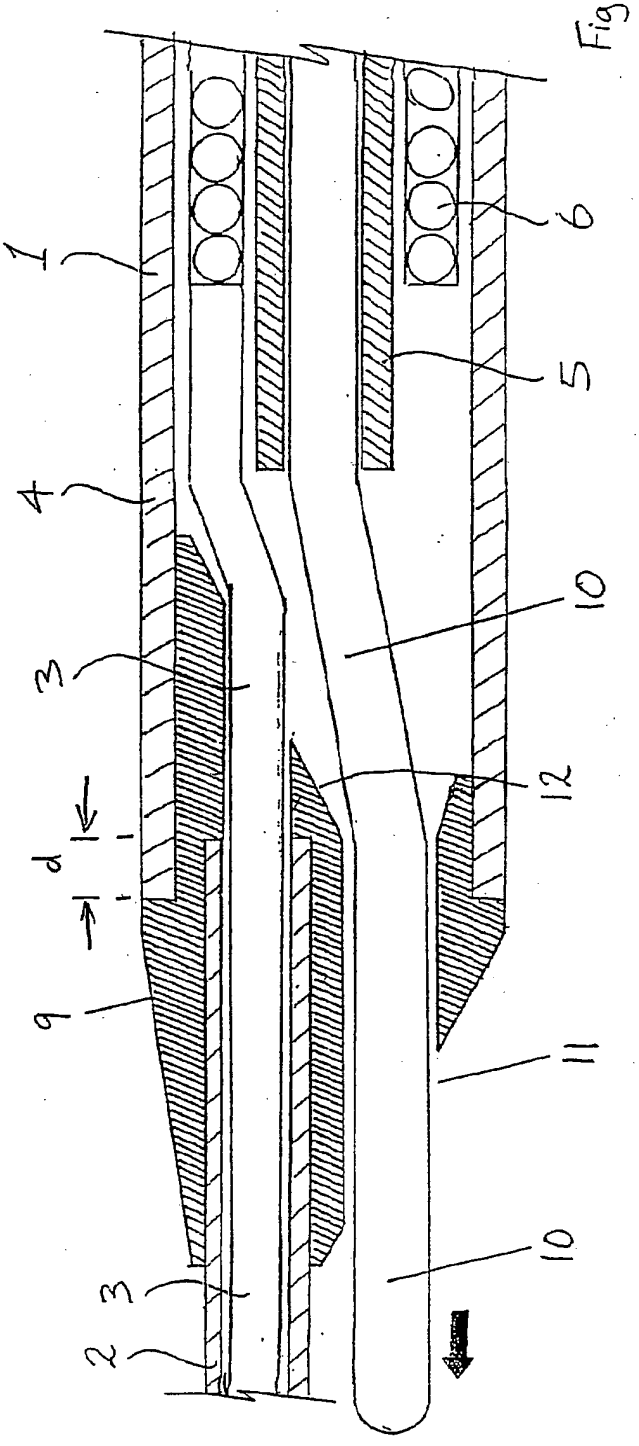
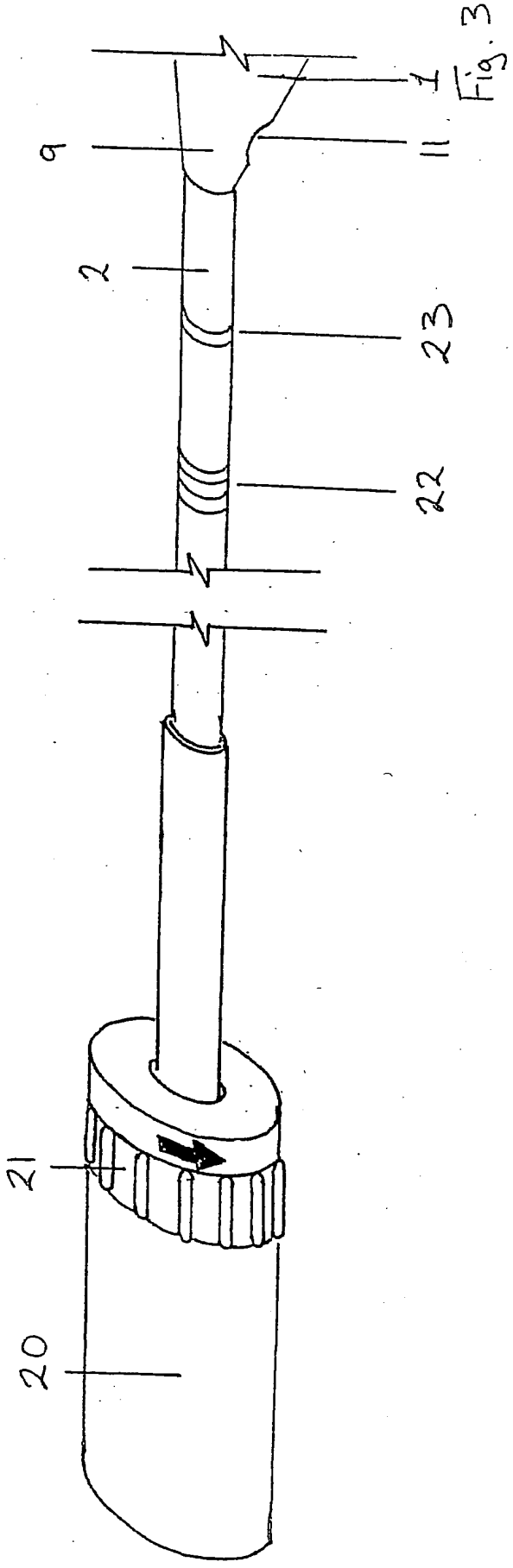


Fig. 2(g)



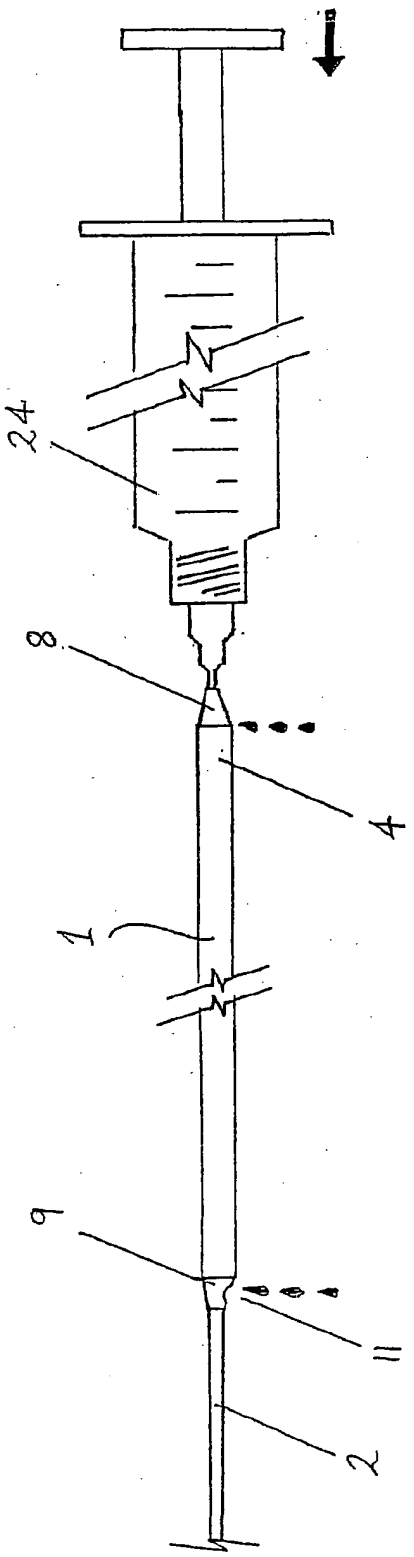


Fig. 3(a)

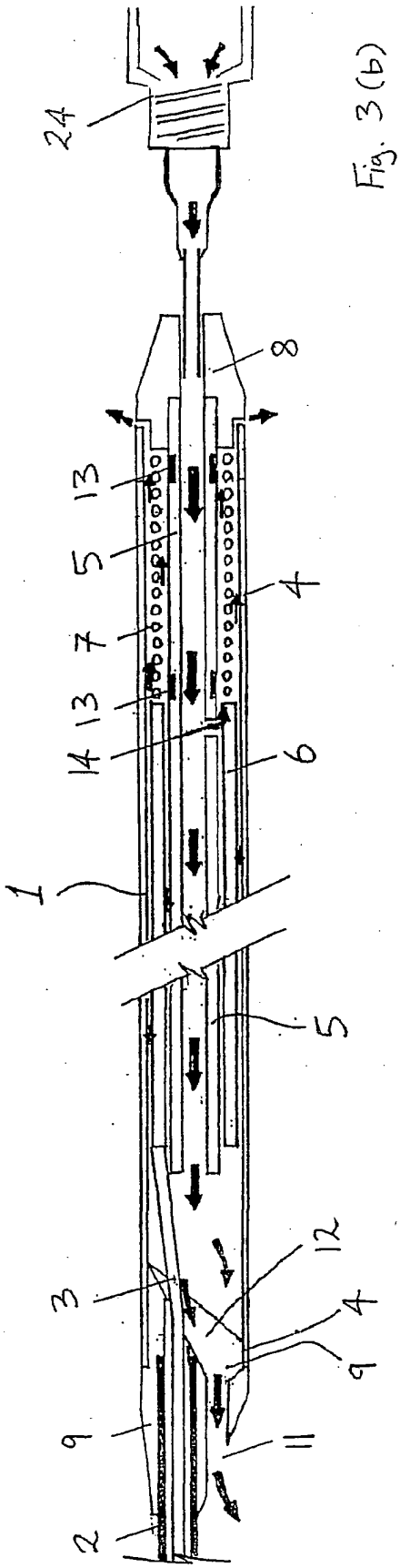


Fig. 3(b)

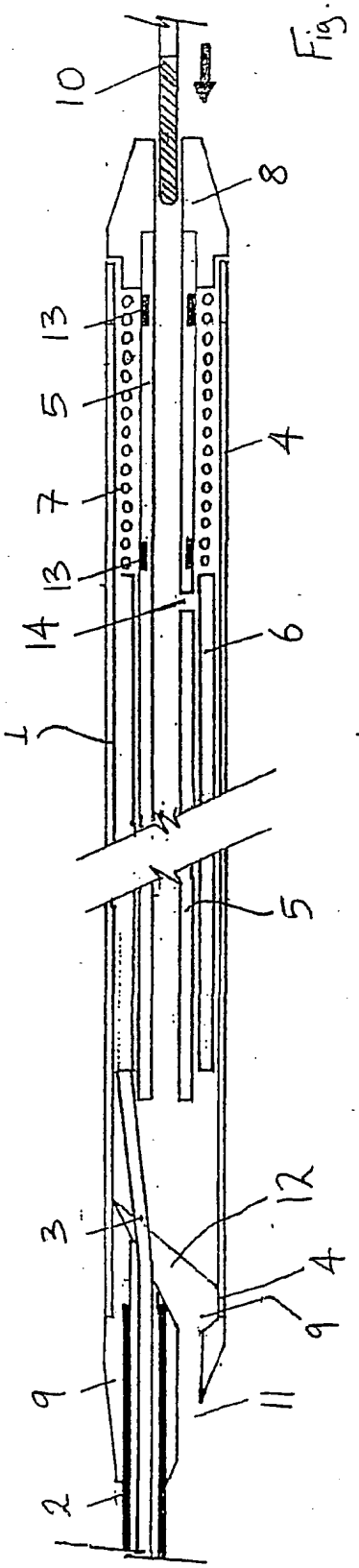

10
8
13
5
7
13
14
4
6
1
5
3
12
4
9
9
11
2

Fig. 3(c)

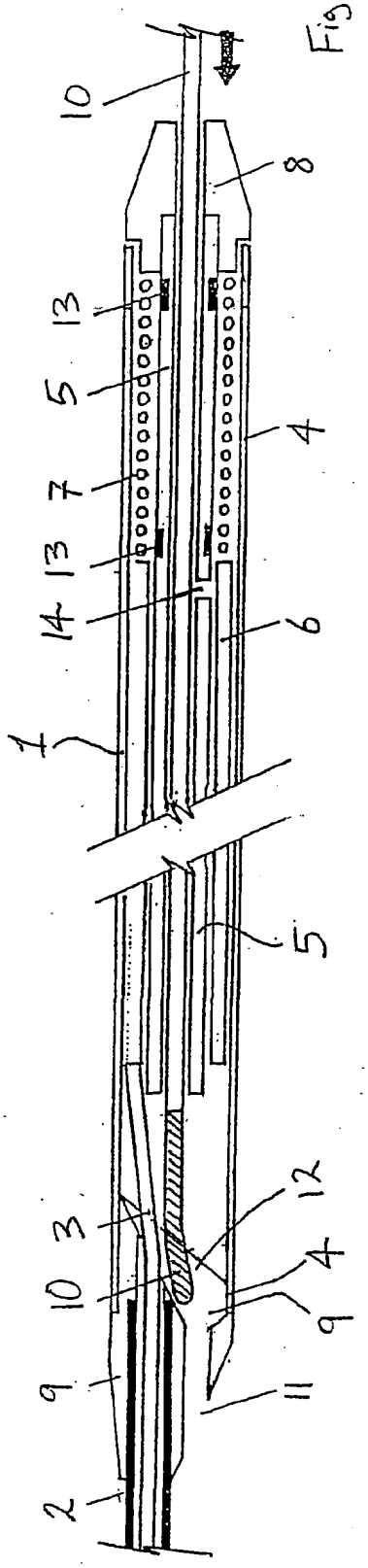
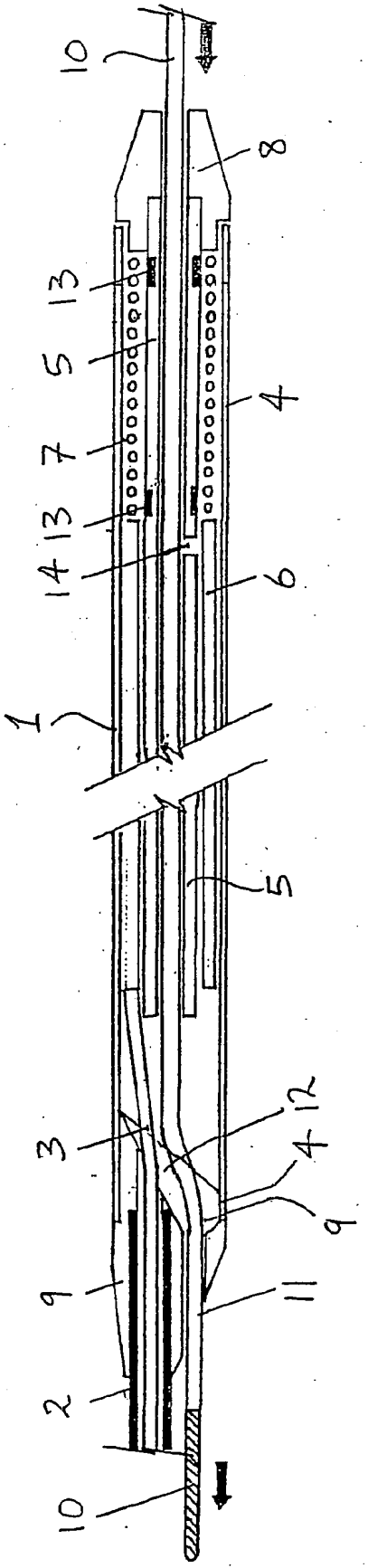

10
8
13
5
7
13
14
4
6
1
5
3
12
10
4
9
9
11
2

Fig. 3(d)


10
8
13
5
7
13
14
4
6
1
5
3
12
4
9
9
11
2
10

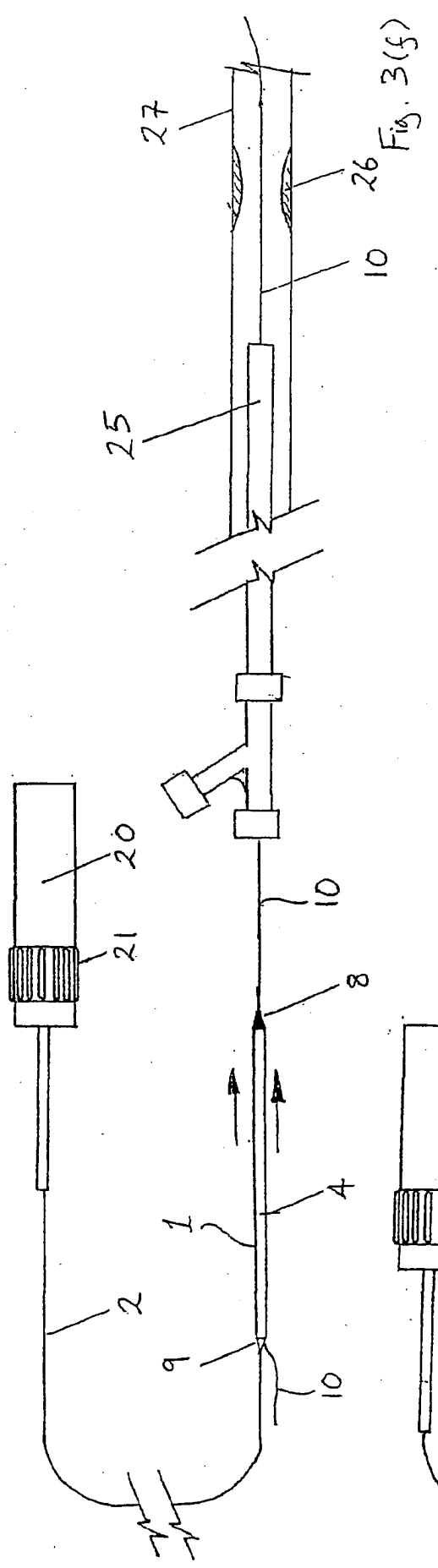


Fig. 3(f)

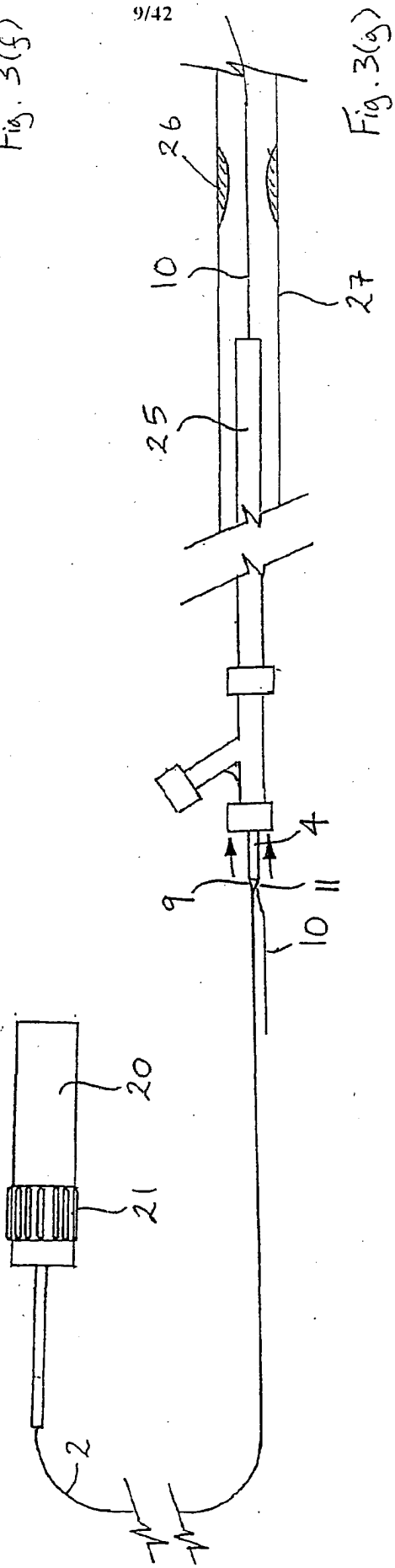


Fig. 3(g)

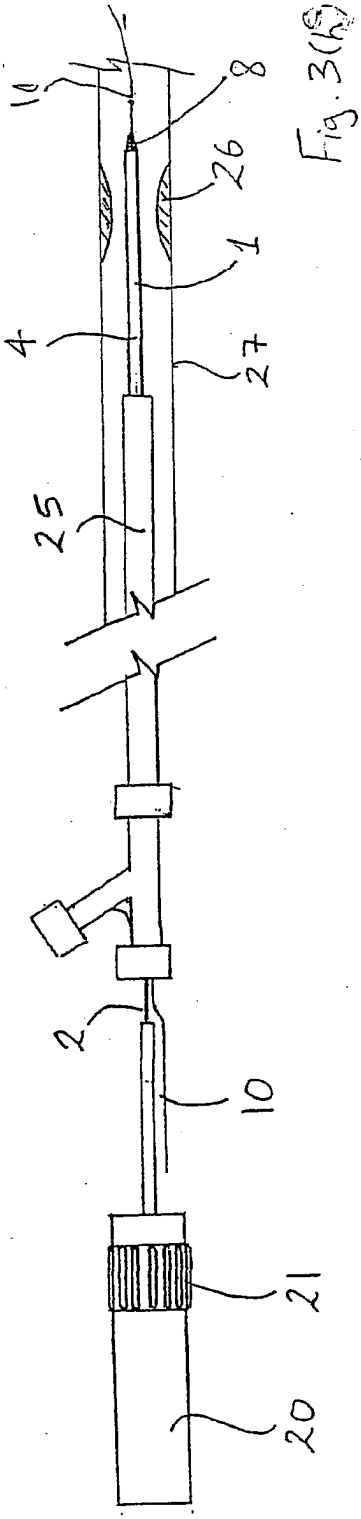


Fig. 3(h)

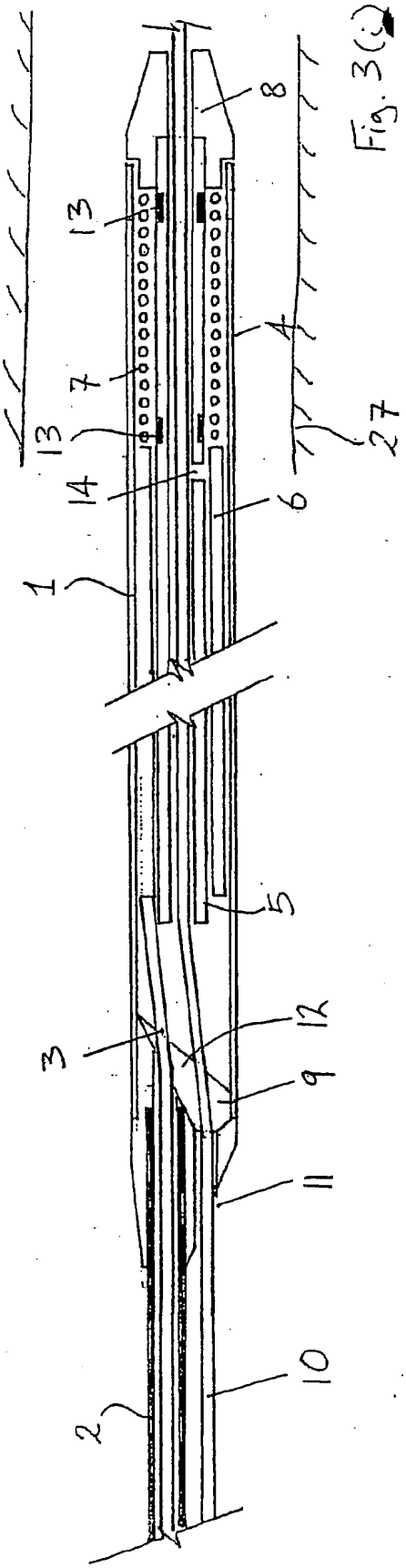


Fig. 3(i)

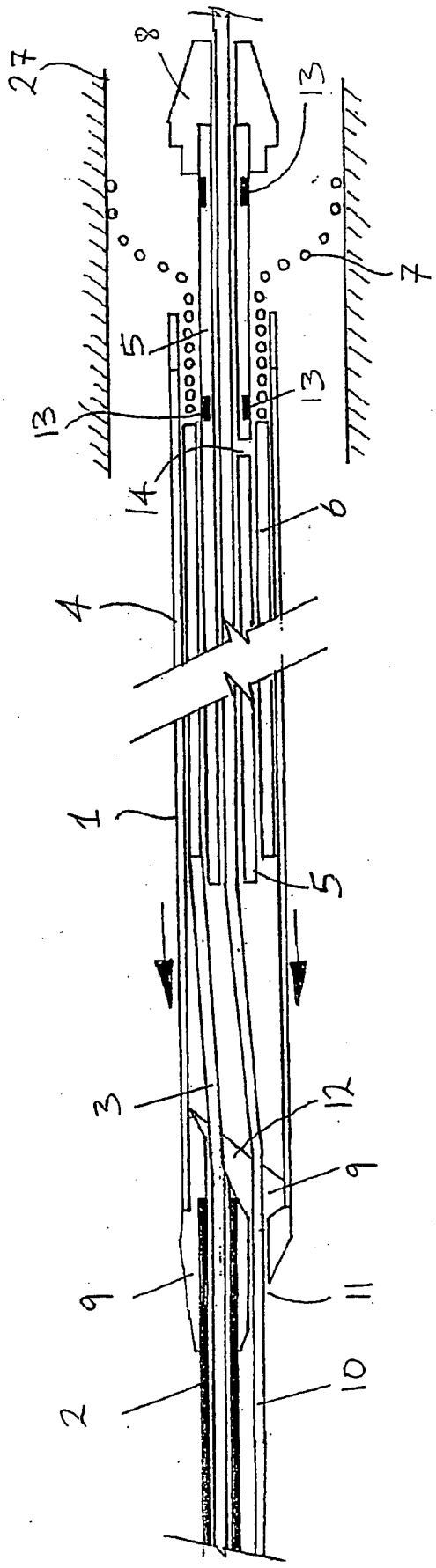


Fig. 3(j)

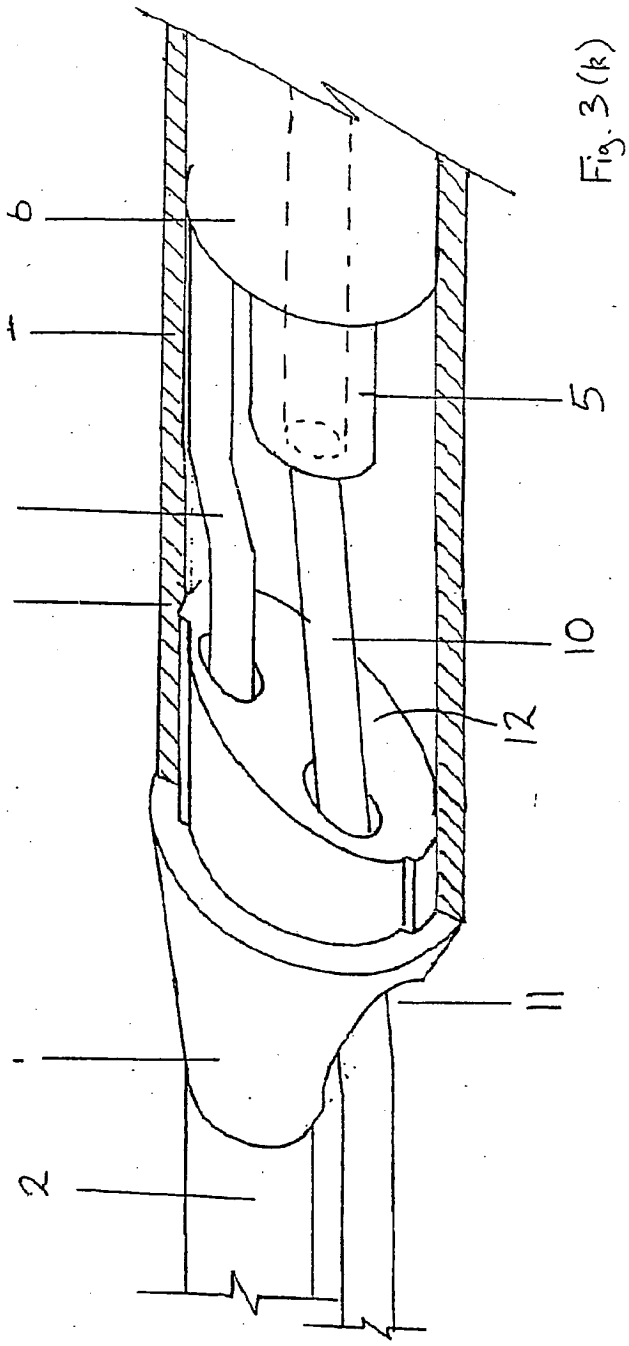


Fig. 3(k)

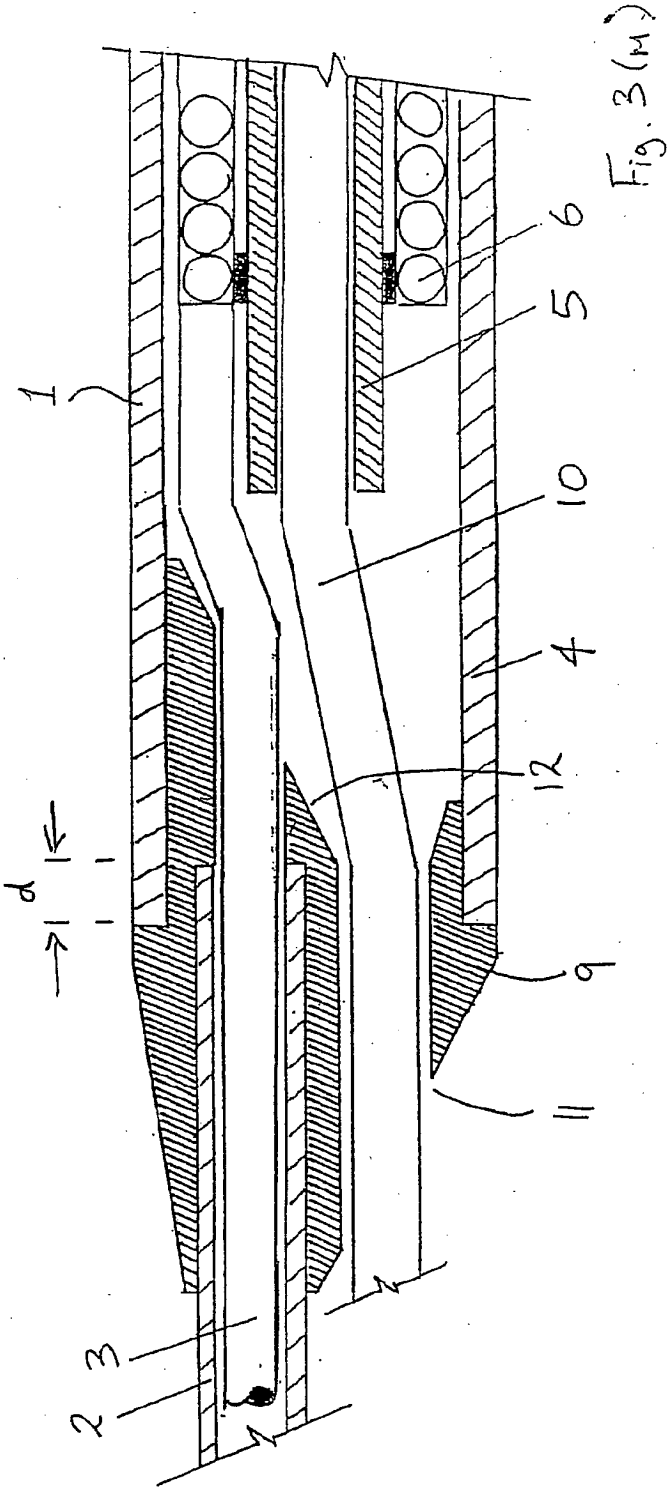


Fig. 3(m)

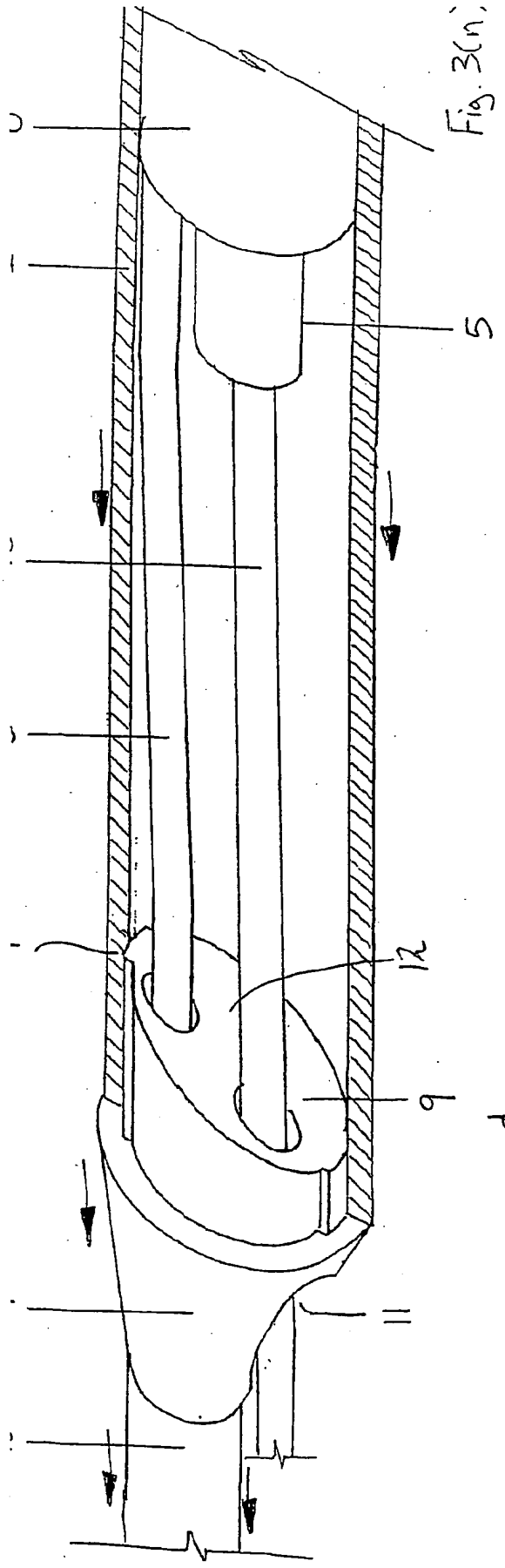


Fig. 3(a)

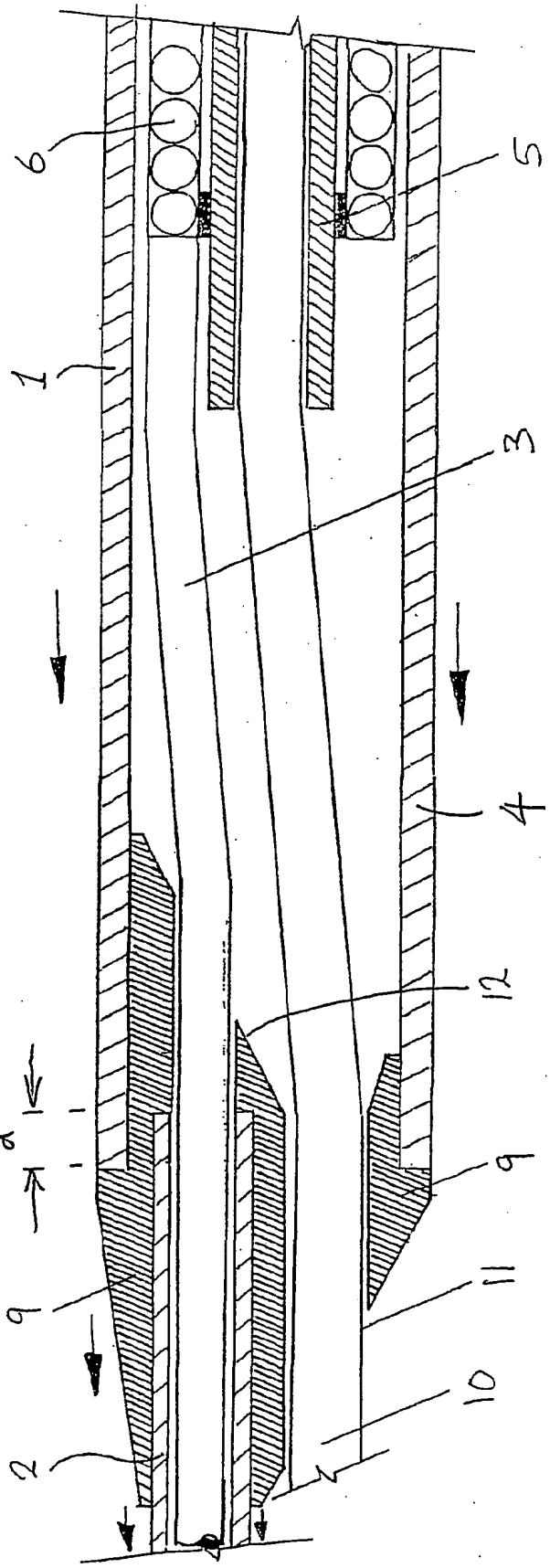


Fig. 3(b)

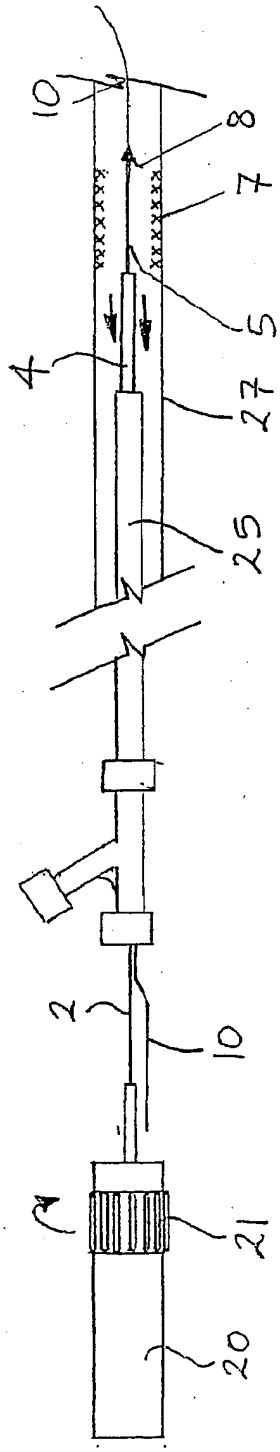


Fig. 3(g)

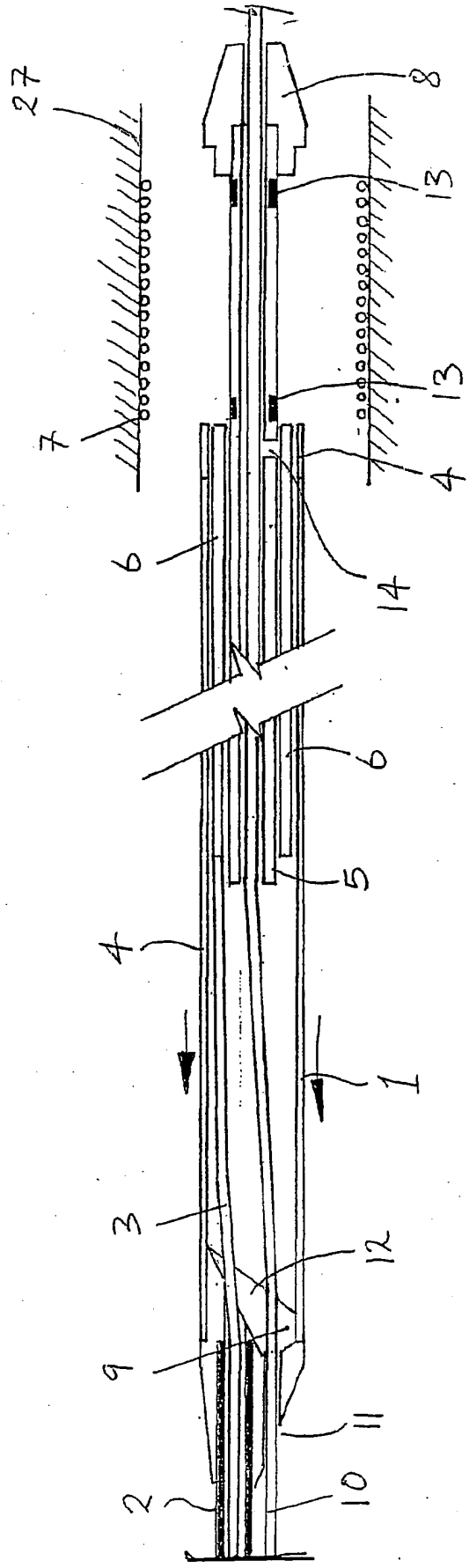


Fig. 3(h)

Fig. 3(s)

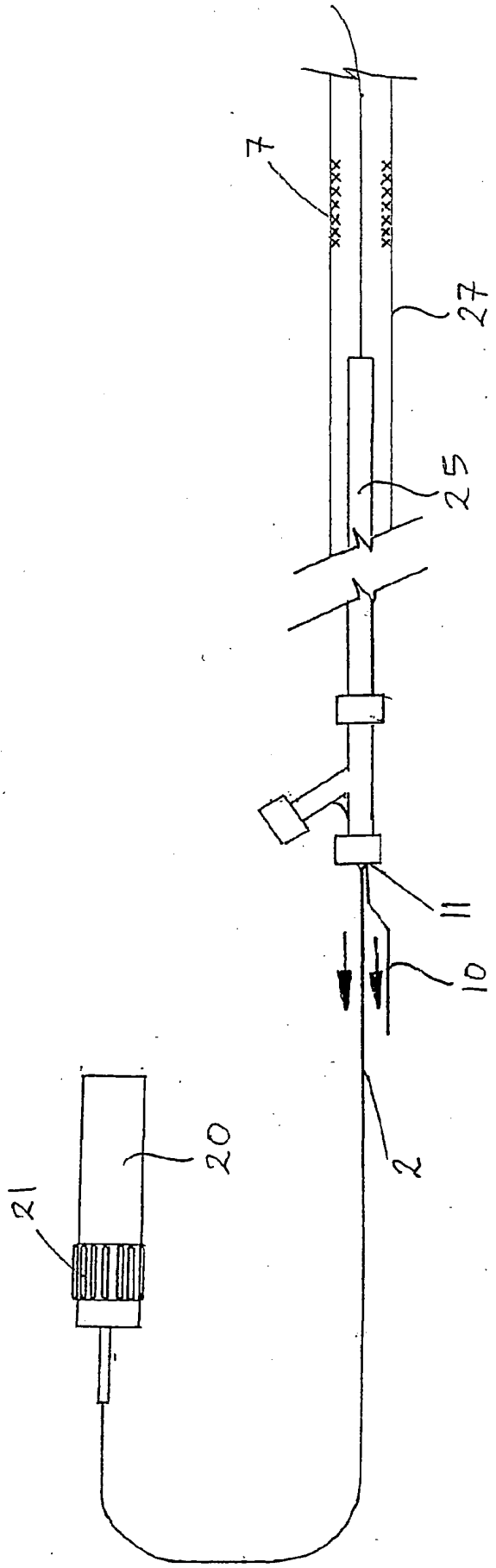
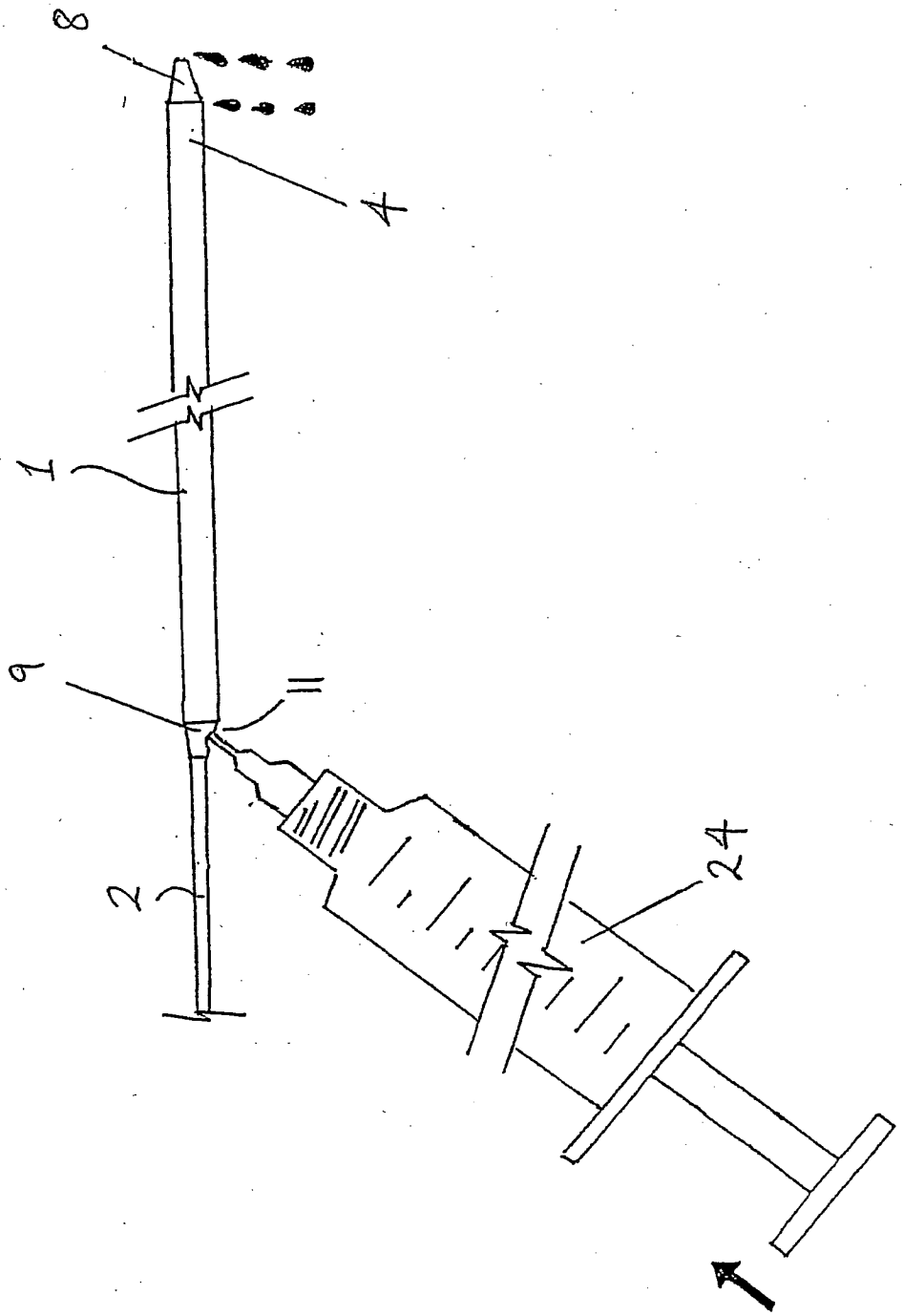


Fig. 3(e)



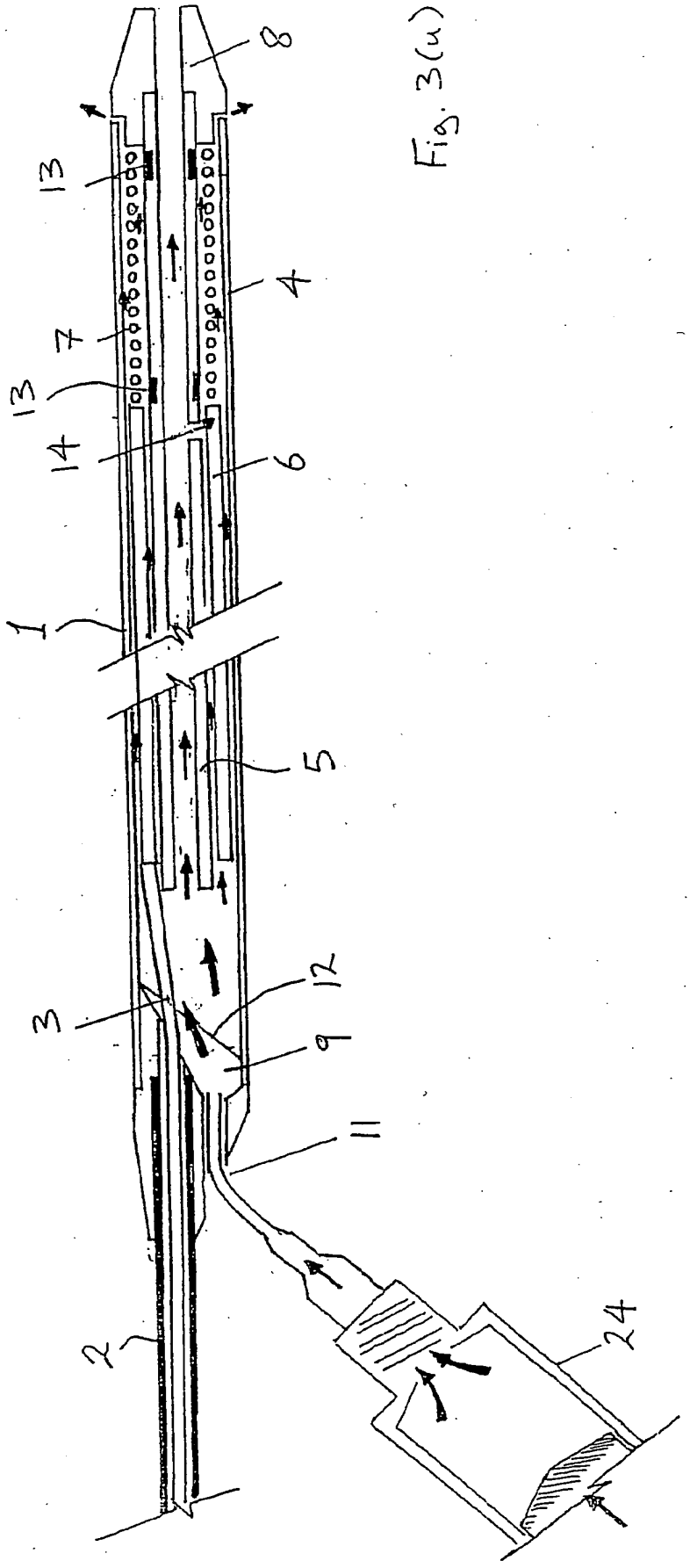
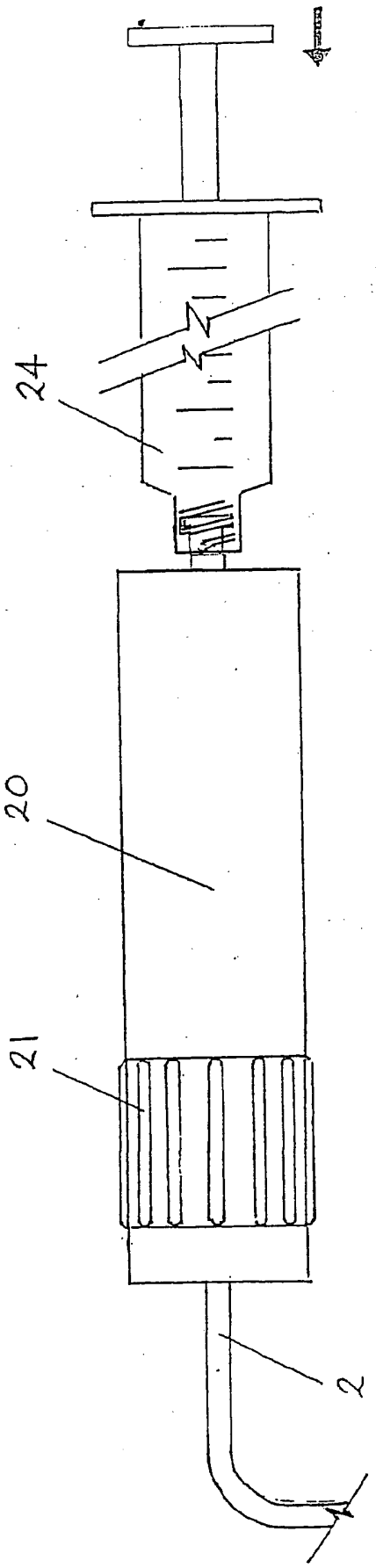
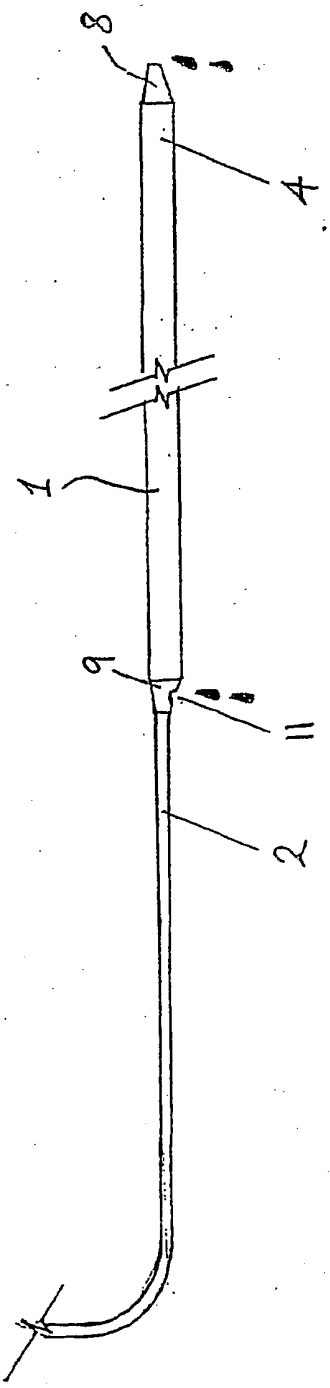


Fig. 3(a)


24
20
21
2


8
4
1
9
2

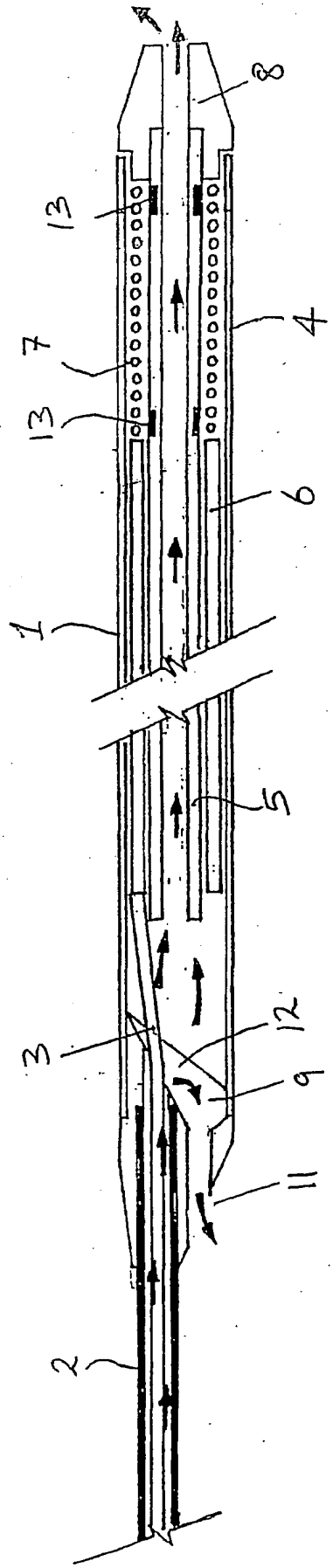
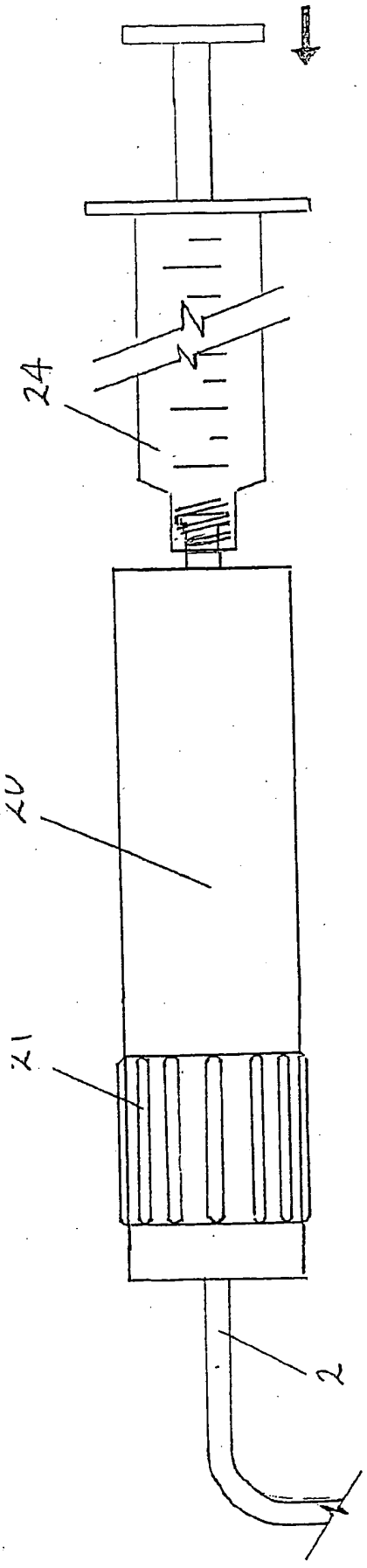


Fig. 3(w)



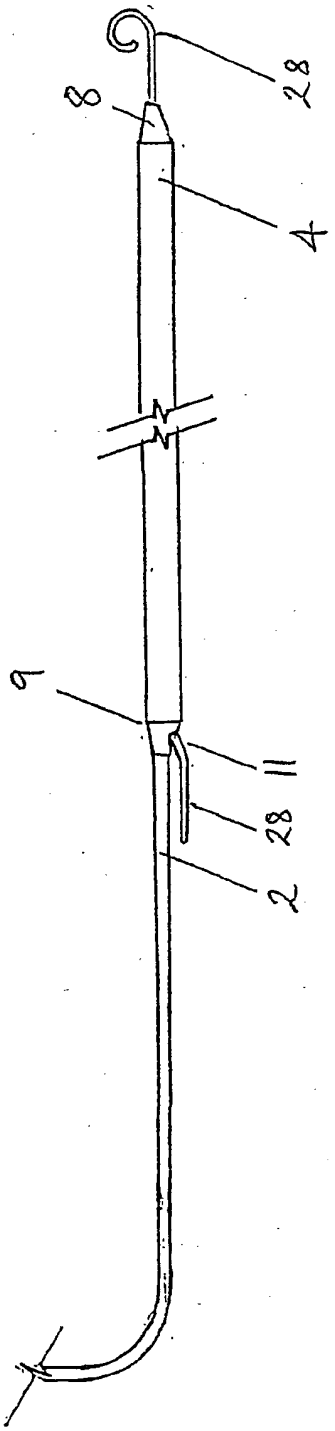


Fig. 3(x)

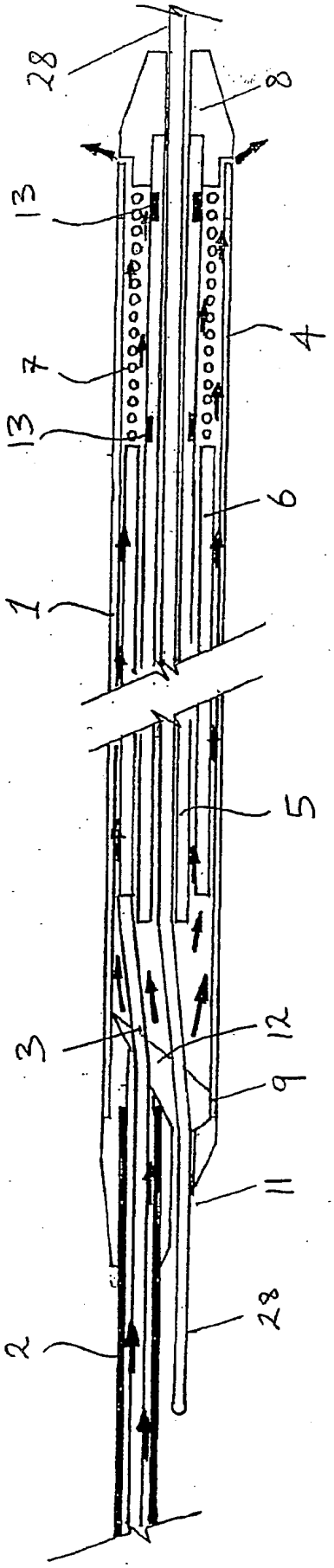


Fig. 3(y)

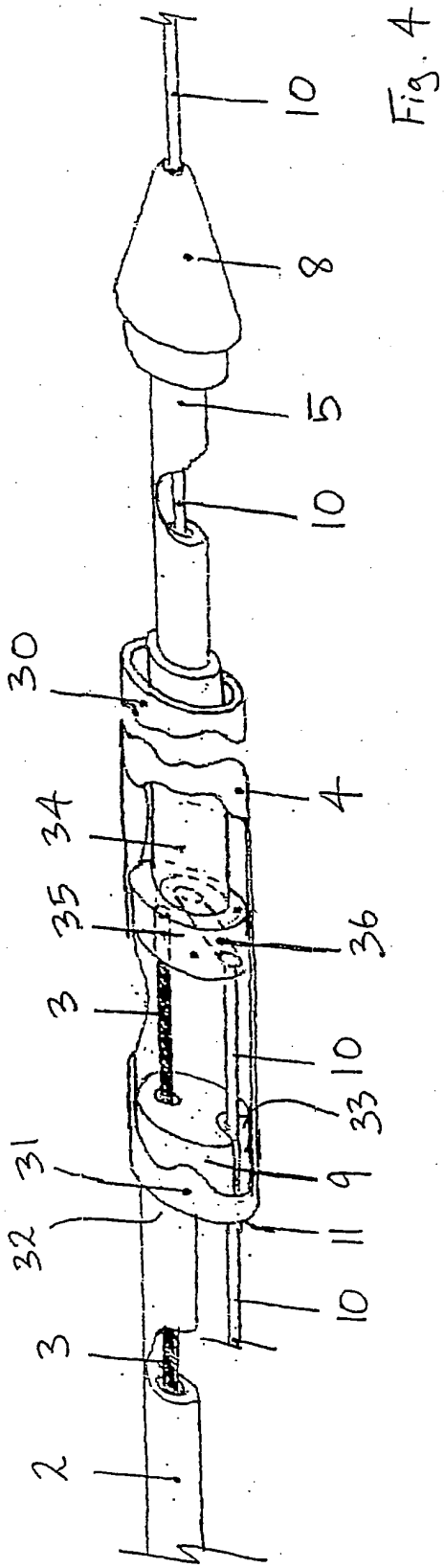


Fig. 4

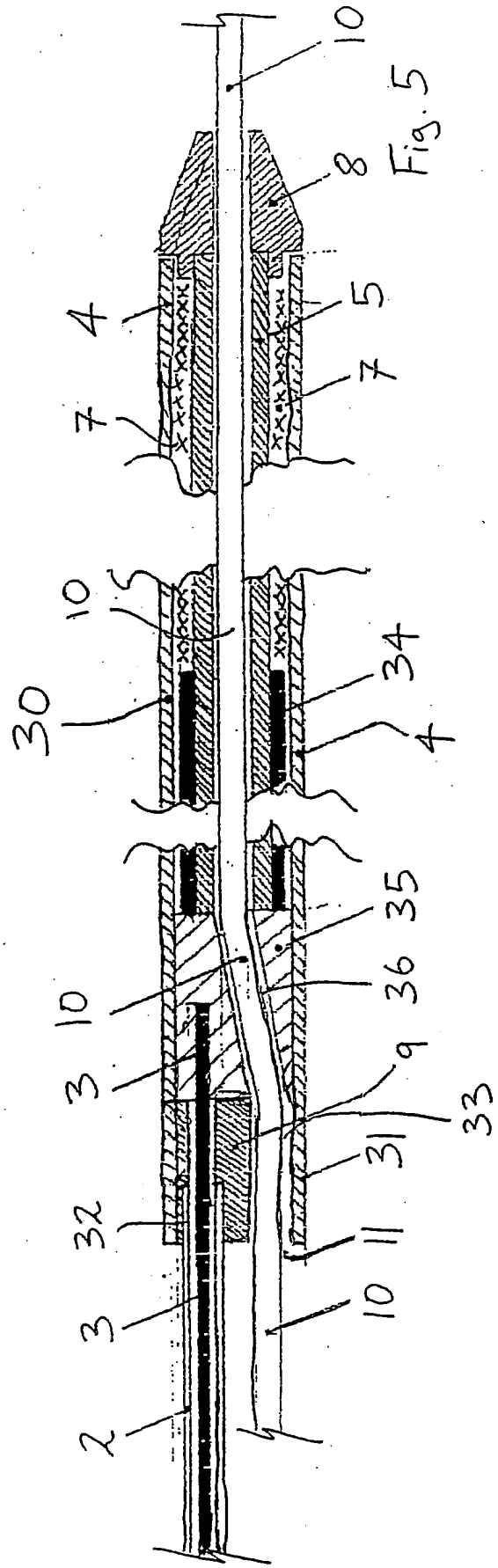


Fig. 5

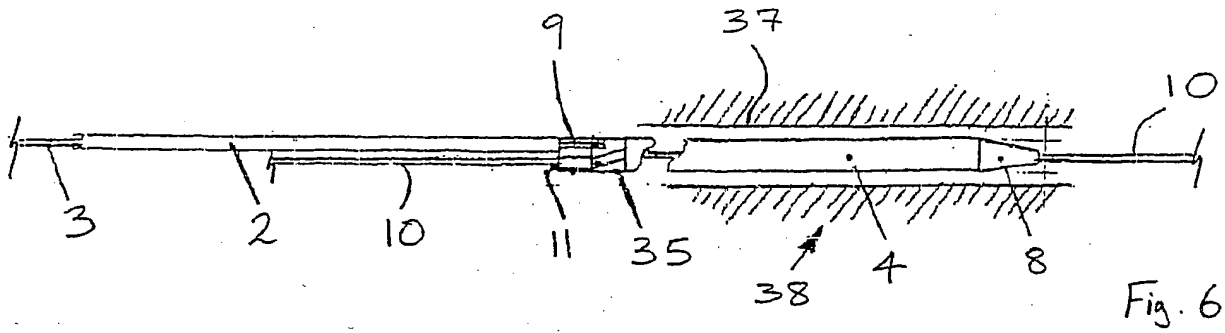


Fig. 6

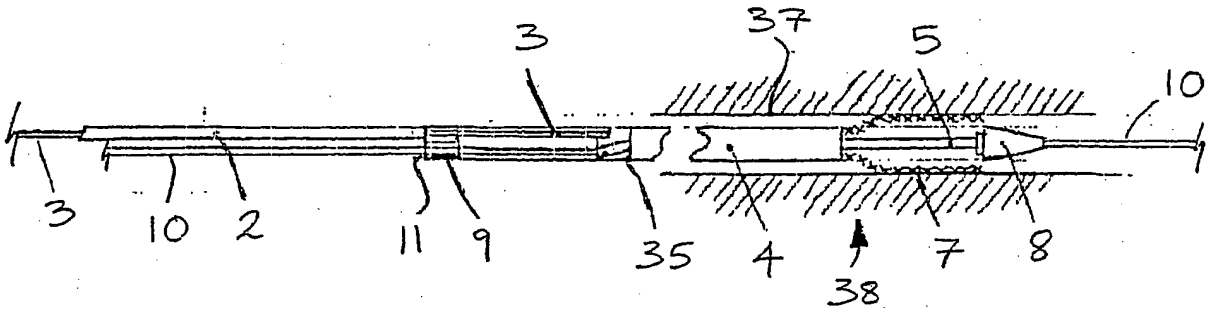


Fig. 7

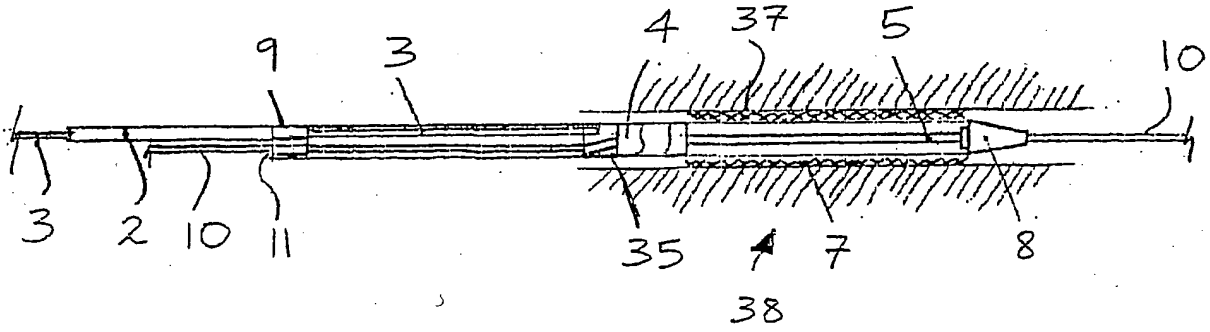


Fig. 8

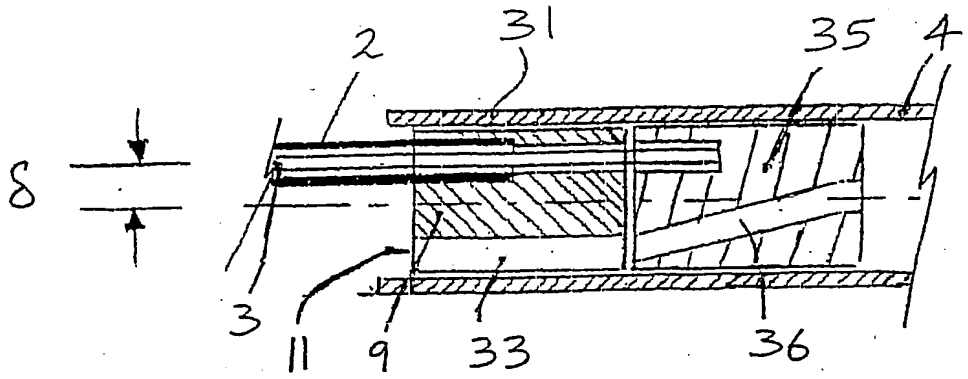


Fig. 9

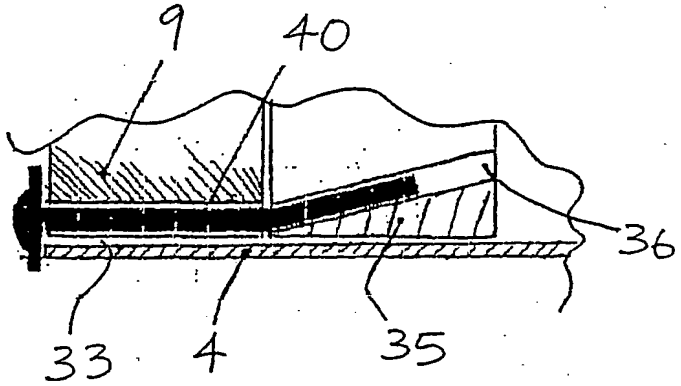


Fig. 10

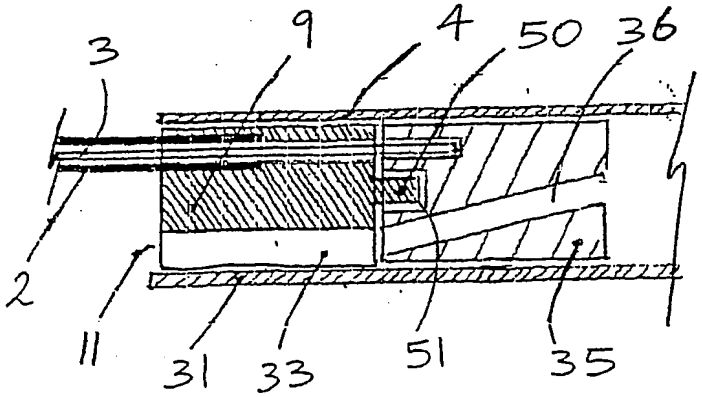


Fig. 11

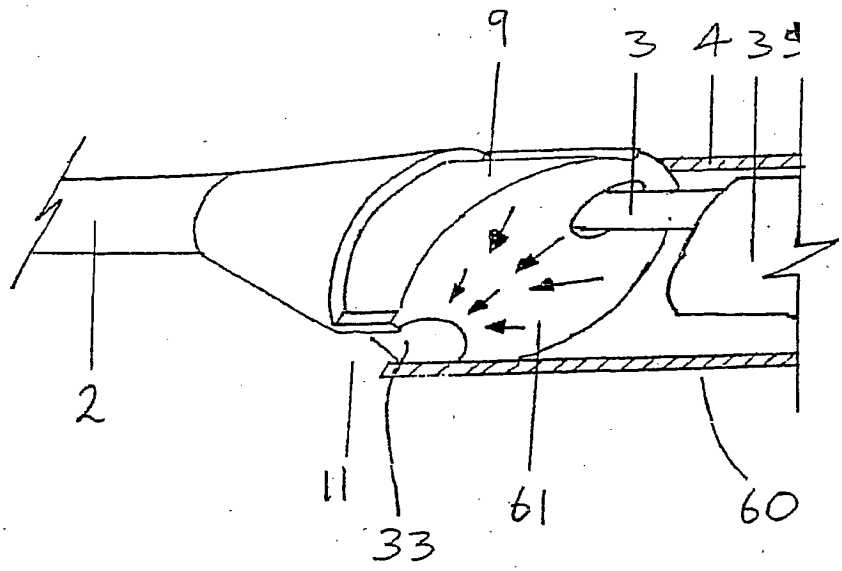


Fig. 12

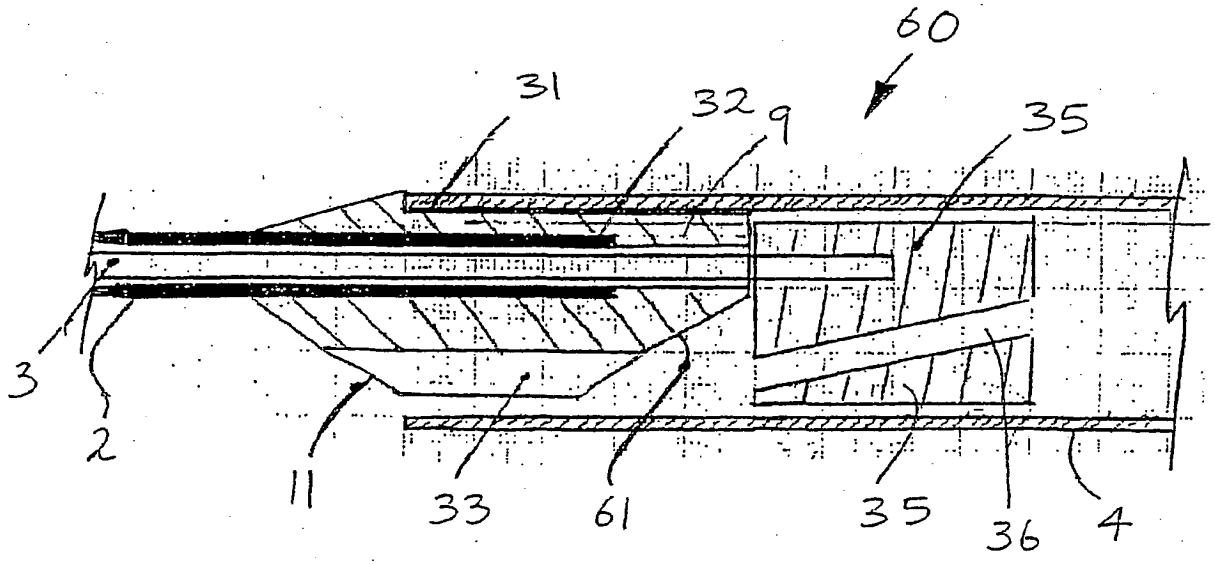


Fig. 13

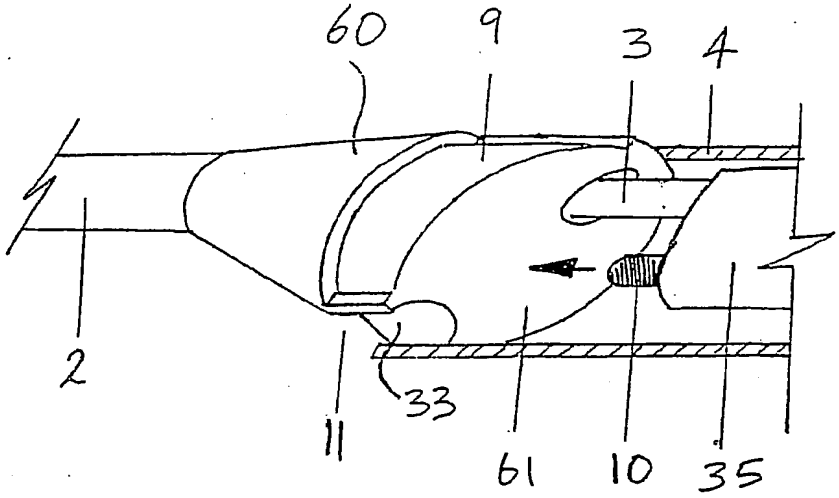


Fig. 13(a)

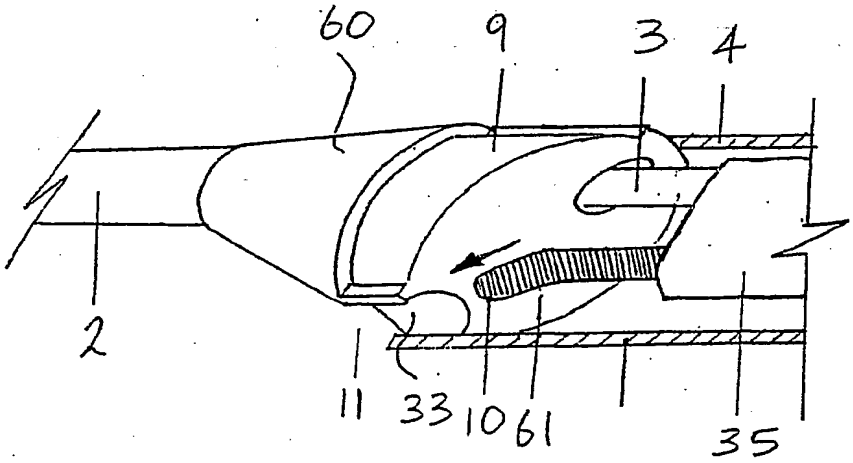


Fig. 13(b)

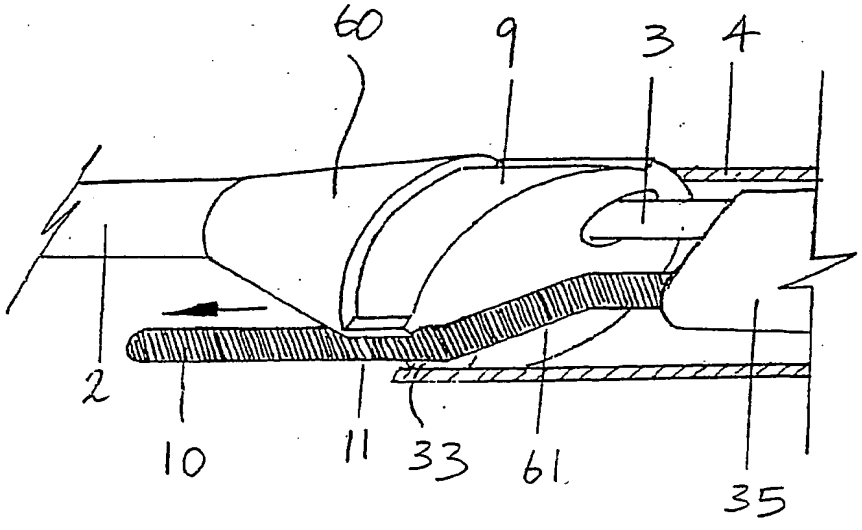


Fig. 13(c)

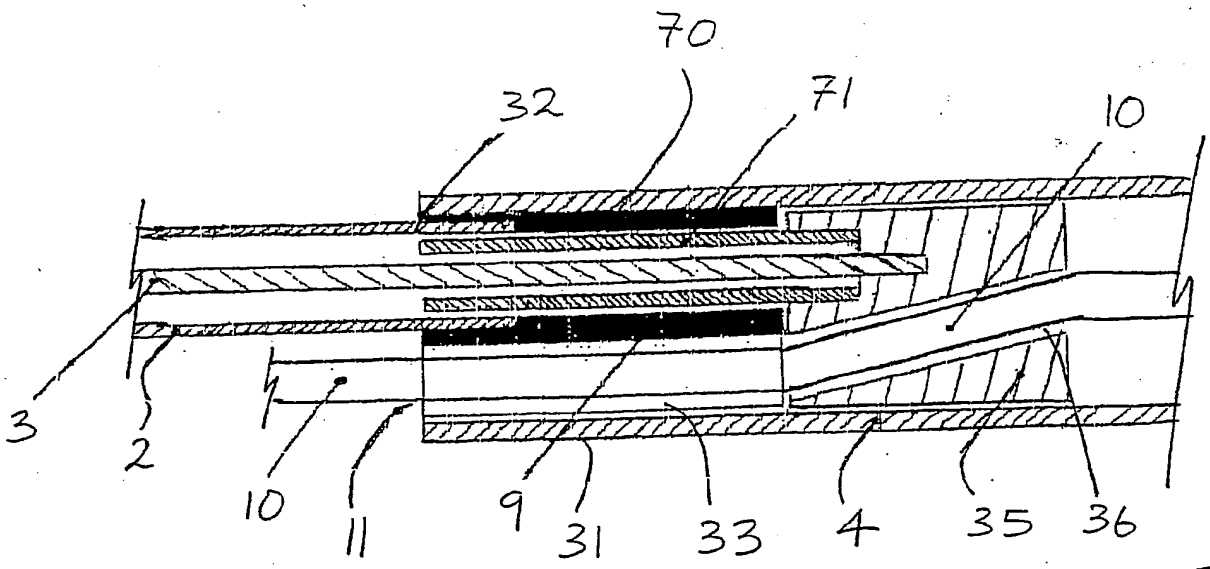


Fig. 14

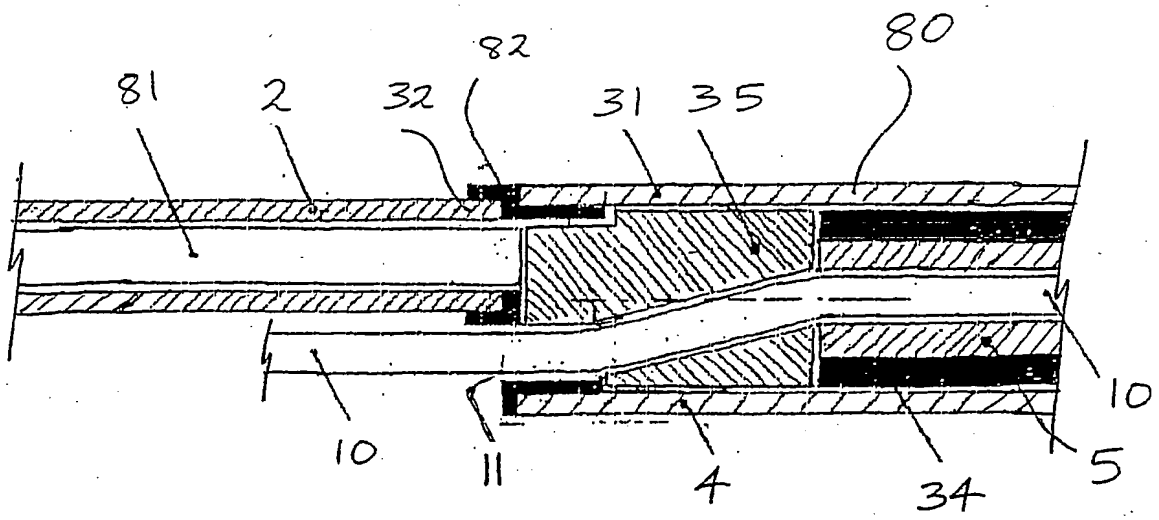


Fig. 15

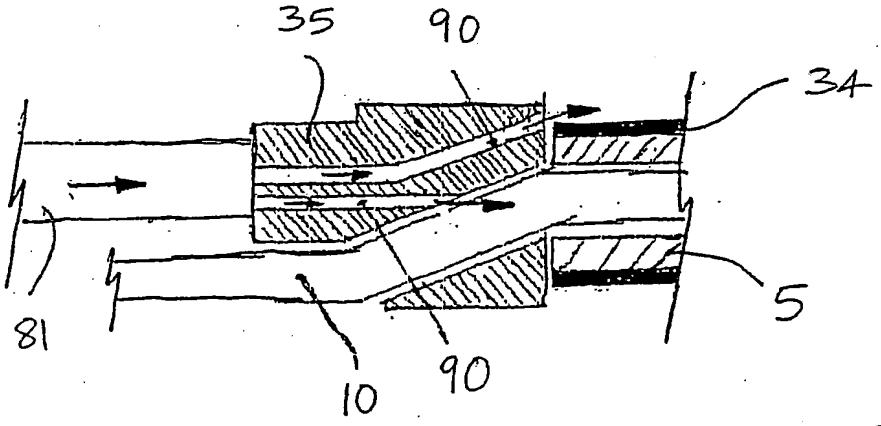


Fig. 16

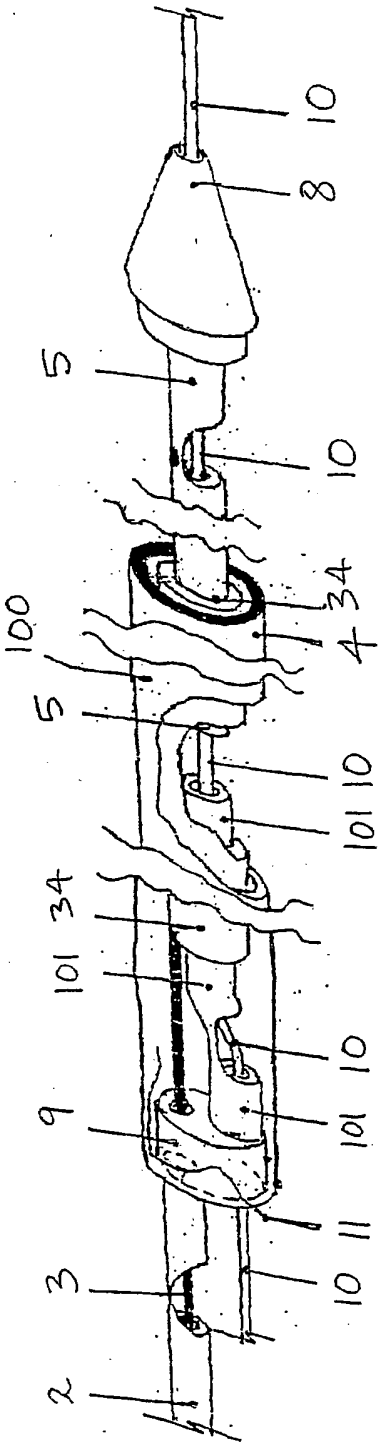


Fig. 17

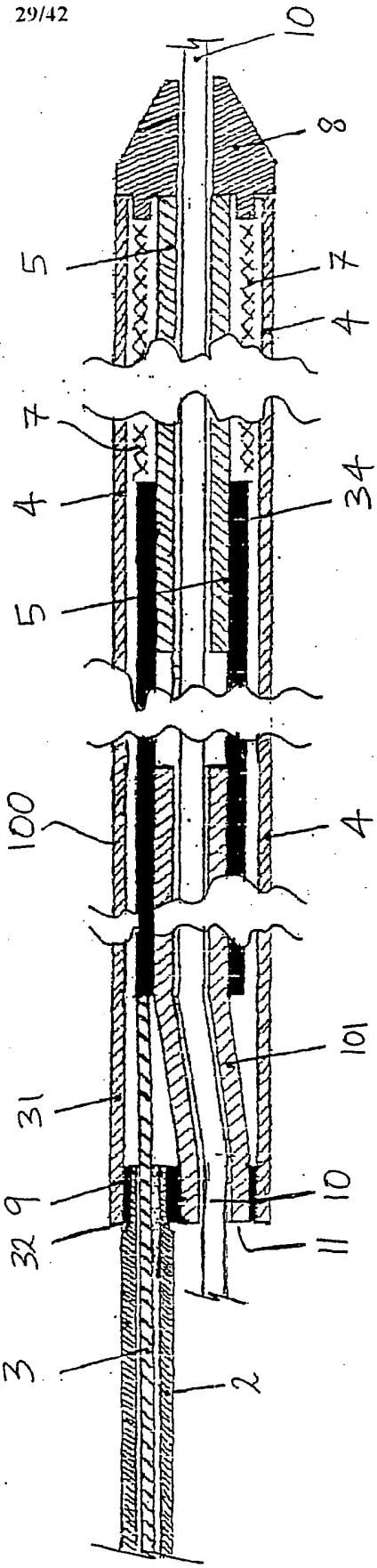


Fig. 18

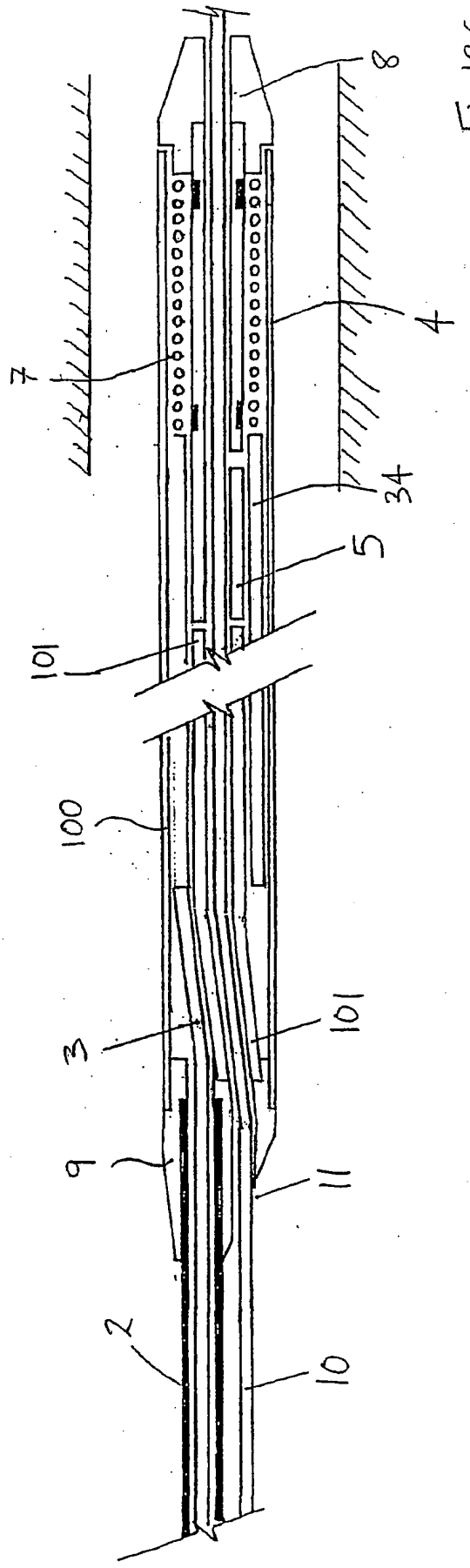


Fig. 19(a)

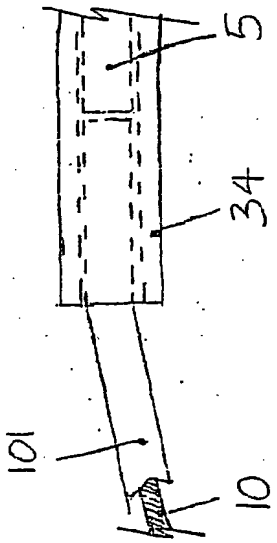


Fig. 19(b)

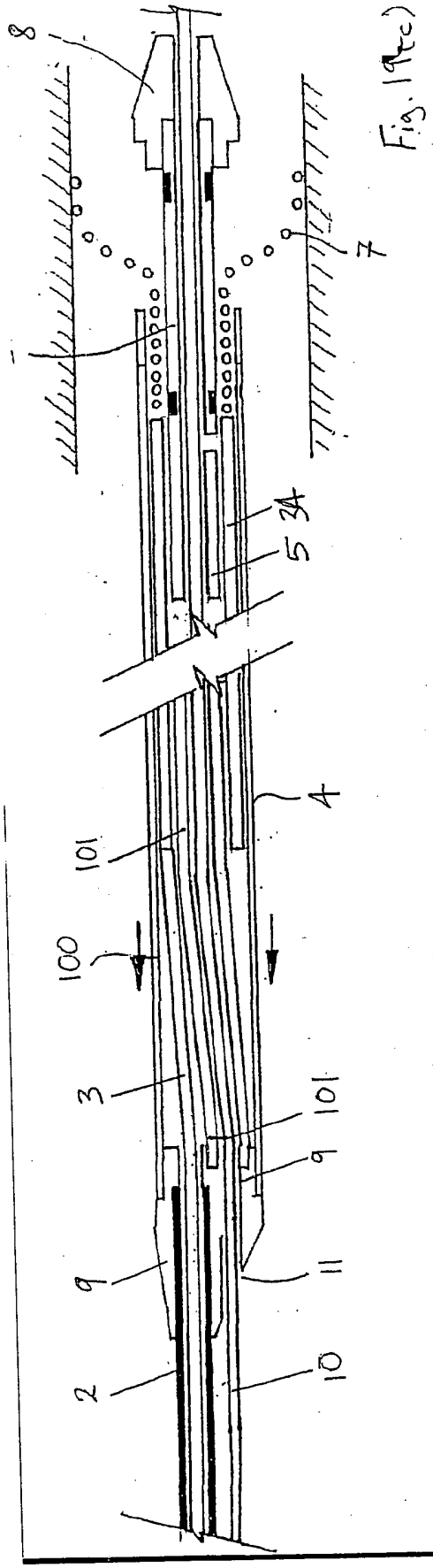


Fig. 19(c)

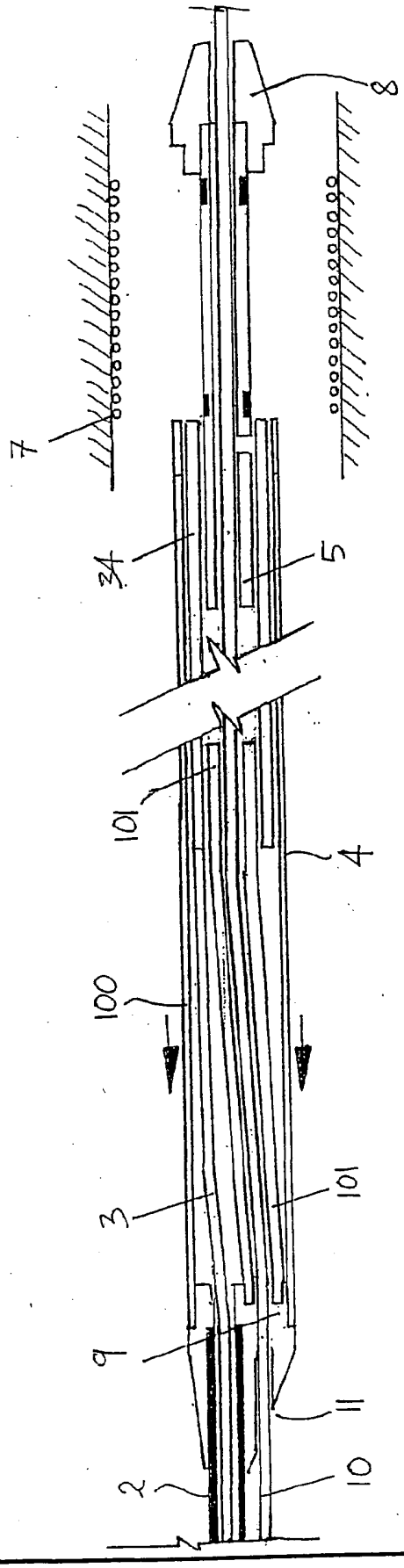


Fig. 19(d)

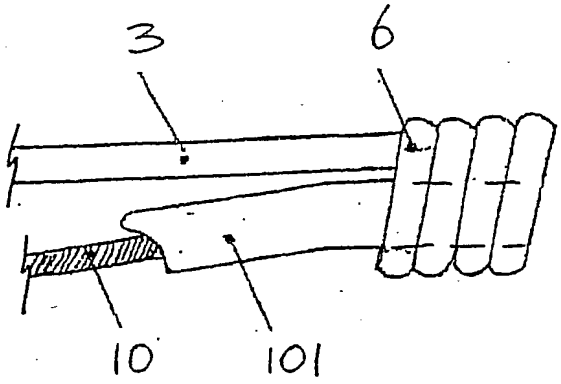


Fig. 20

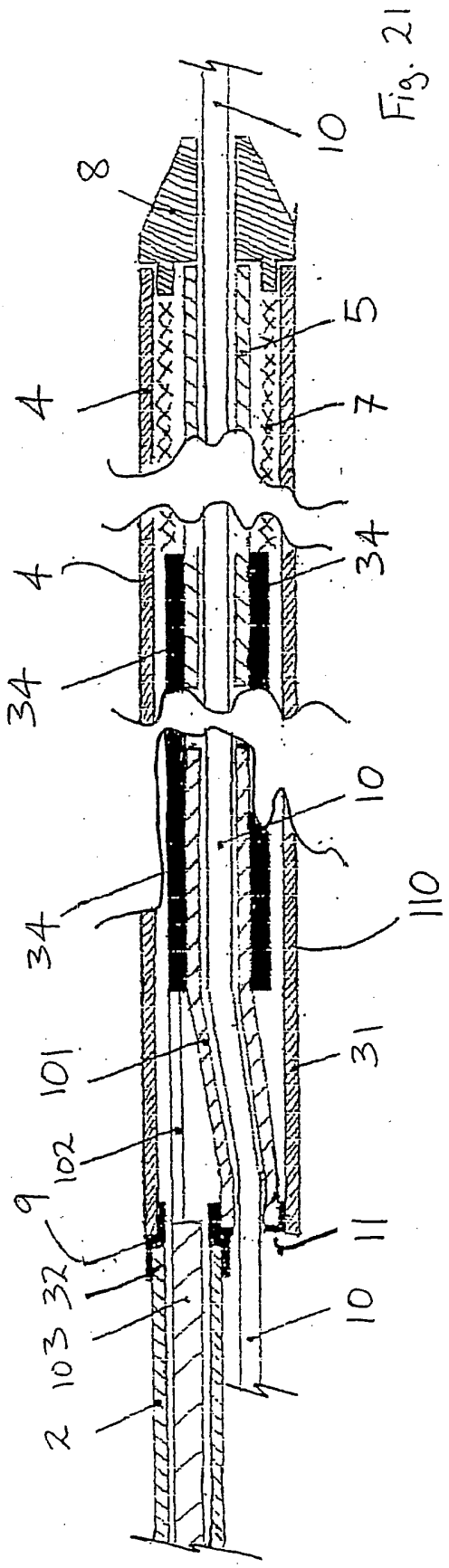


Fig. 21

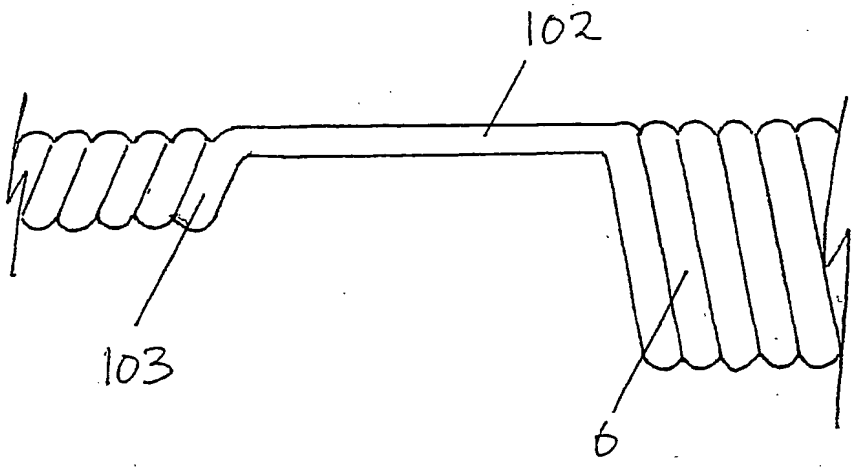


Fig. 22(a)

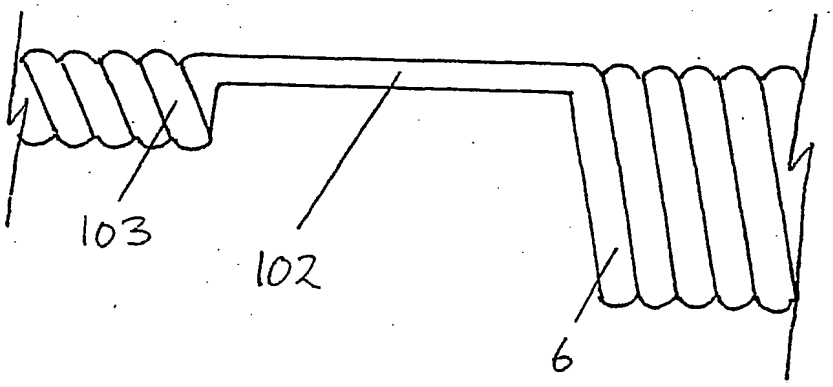


Fig. 22(b)

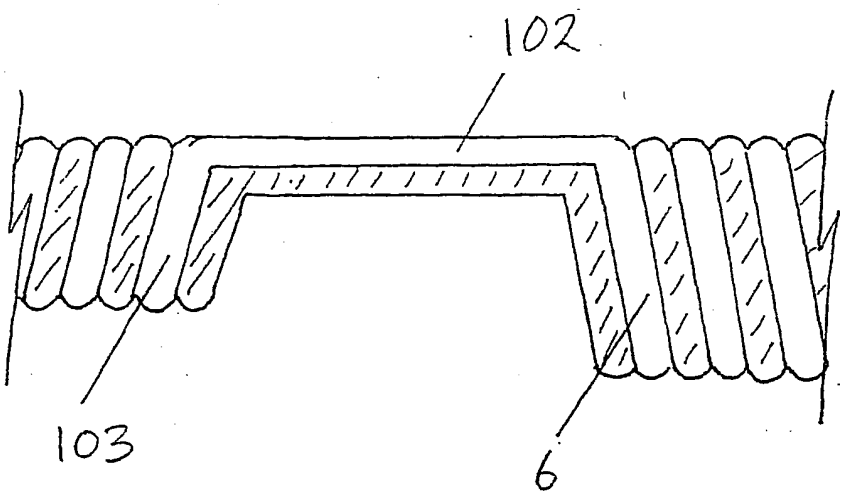


Fig. 23(a)

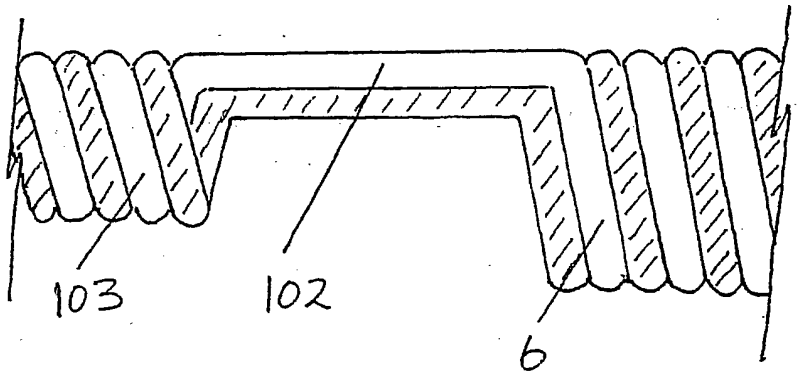


Fig. 23(b)

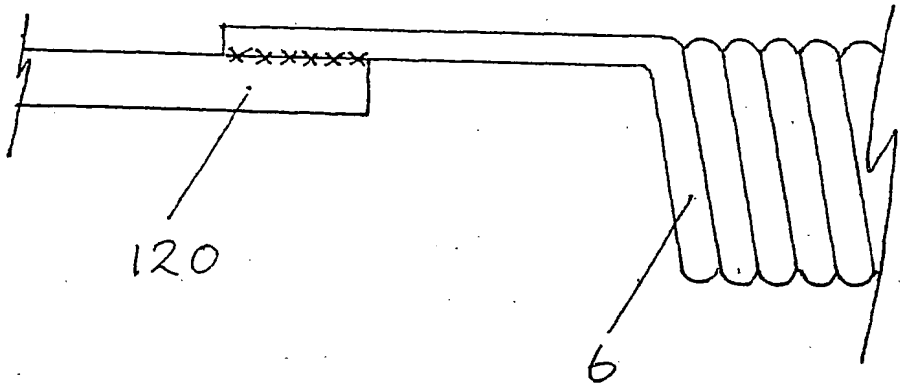


Fig. 24(a)

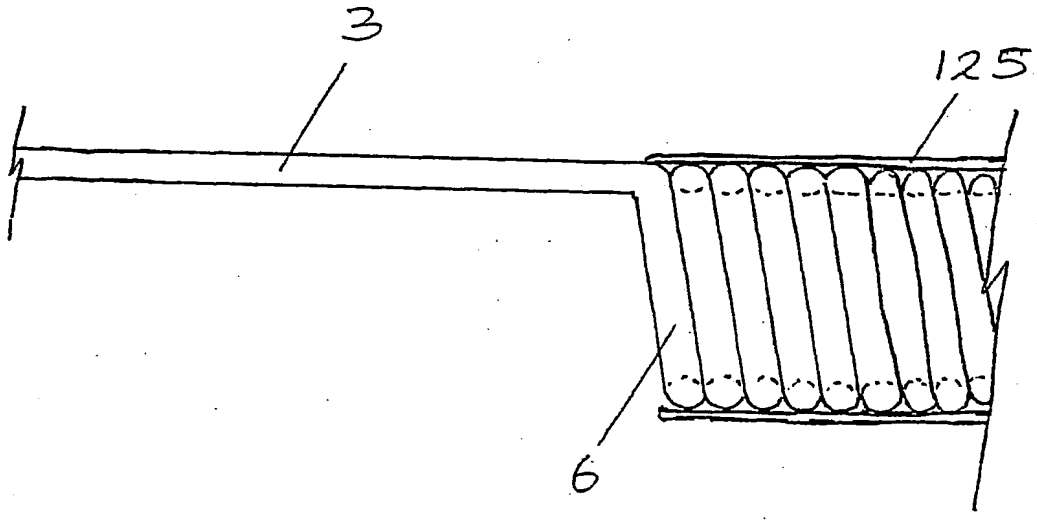


Fig. 24(b)

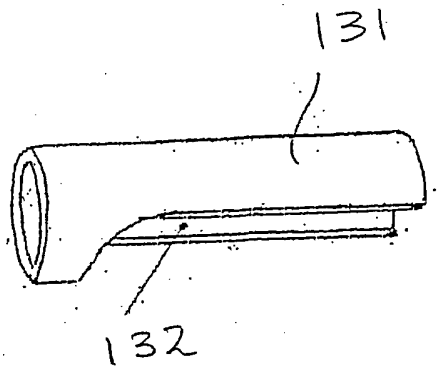


Fig. 25

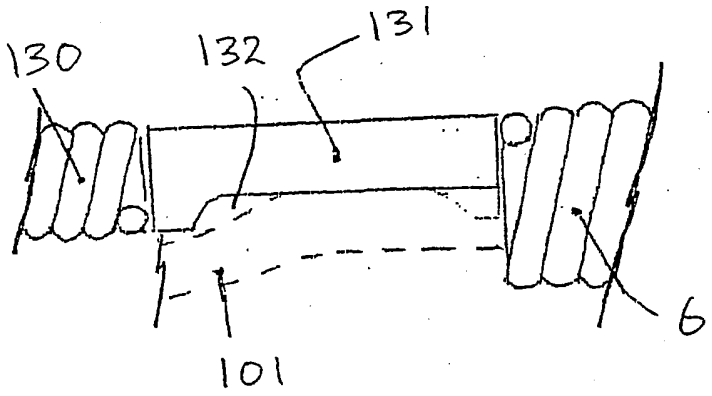


Fig. 26

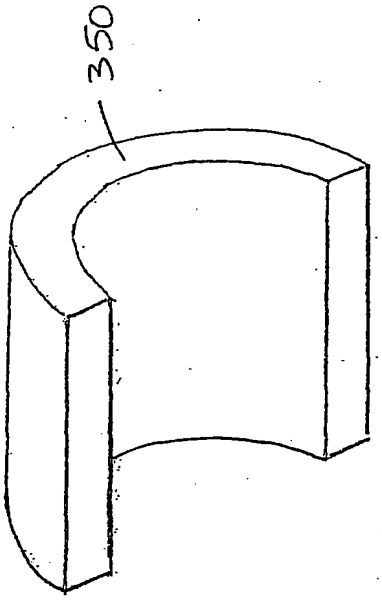


Fig. 26(e)

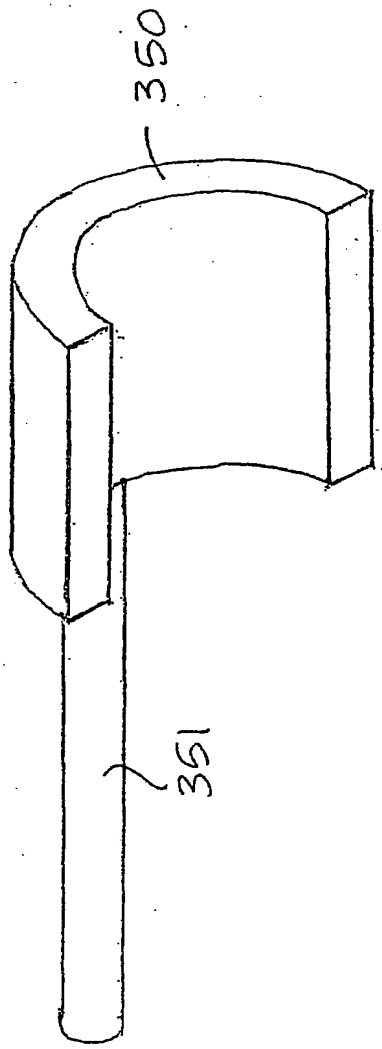


Fig. 26(d)

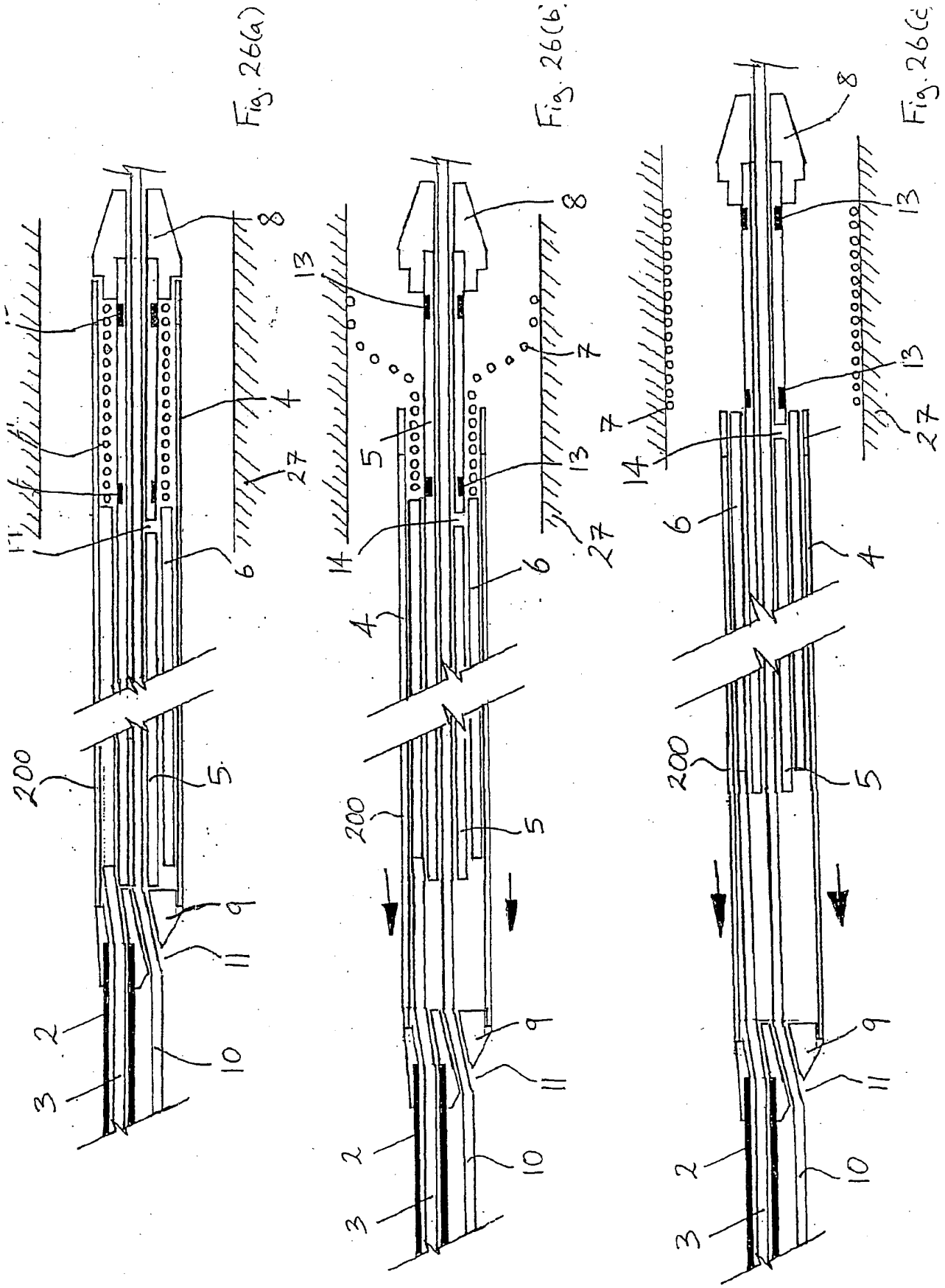


Fig. 26(a)
Fig. 26(b)
Fig. 26(c)
200
2
3
4
5
6
7
8
9
10
11
13
14
27

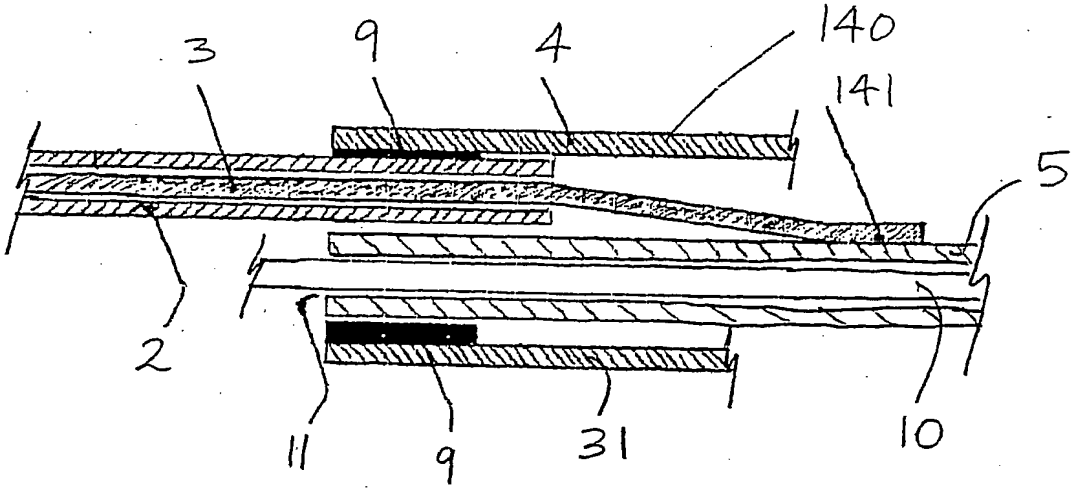


Fig. 27

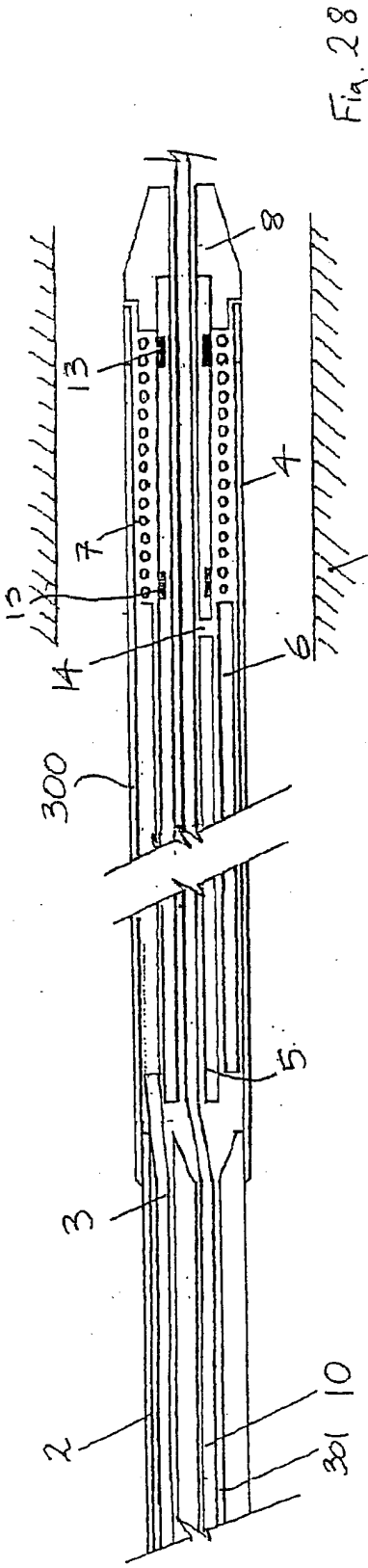


Fig. 28

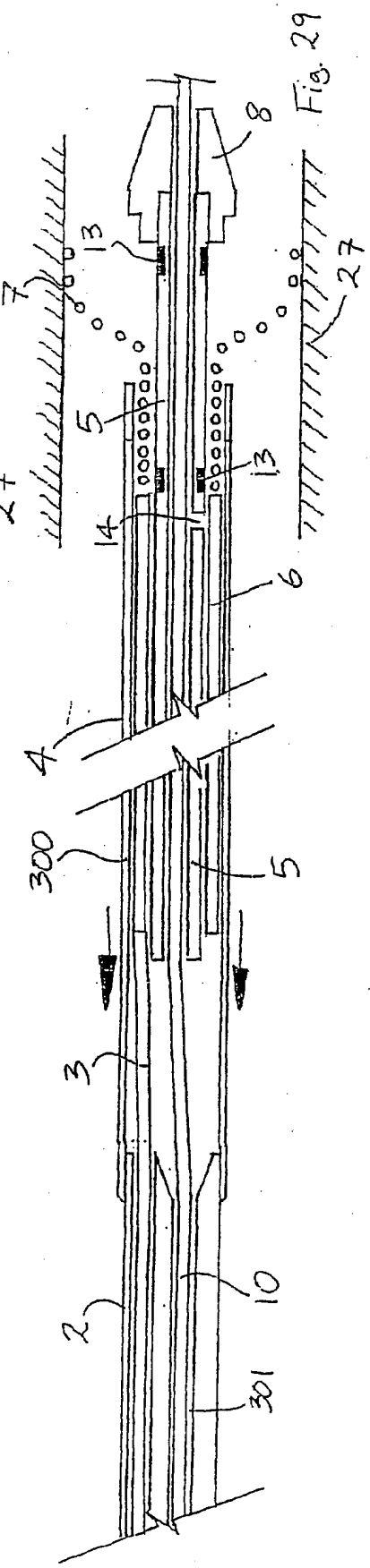


Fig. 29

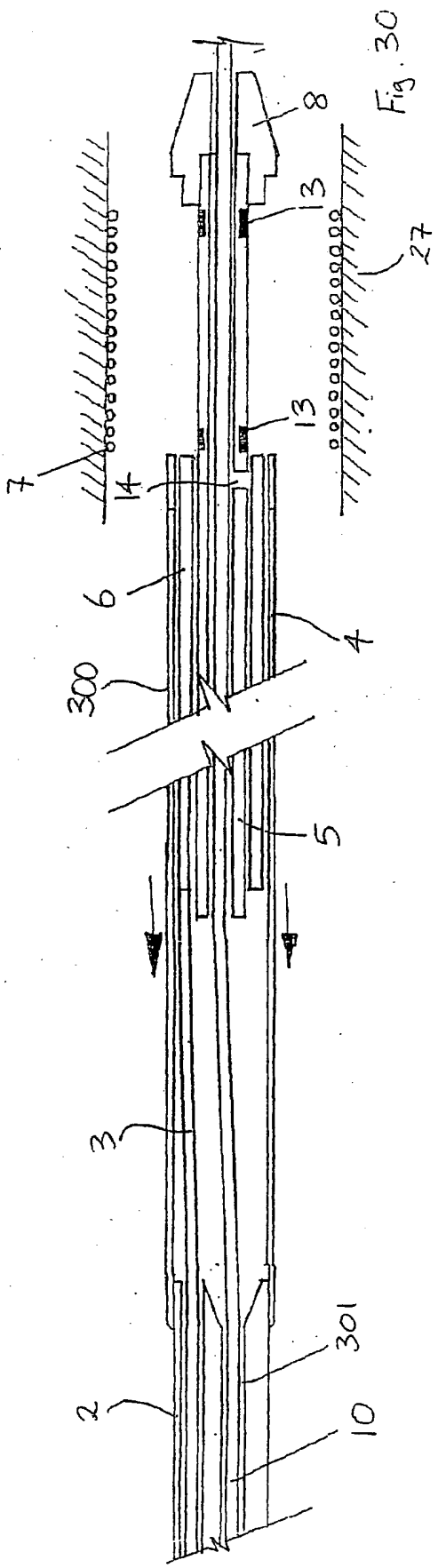


Fig. 30

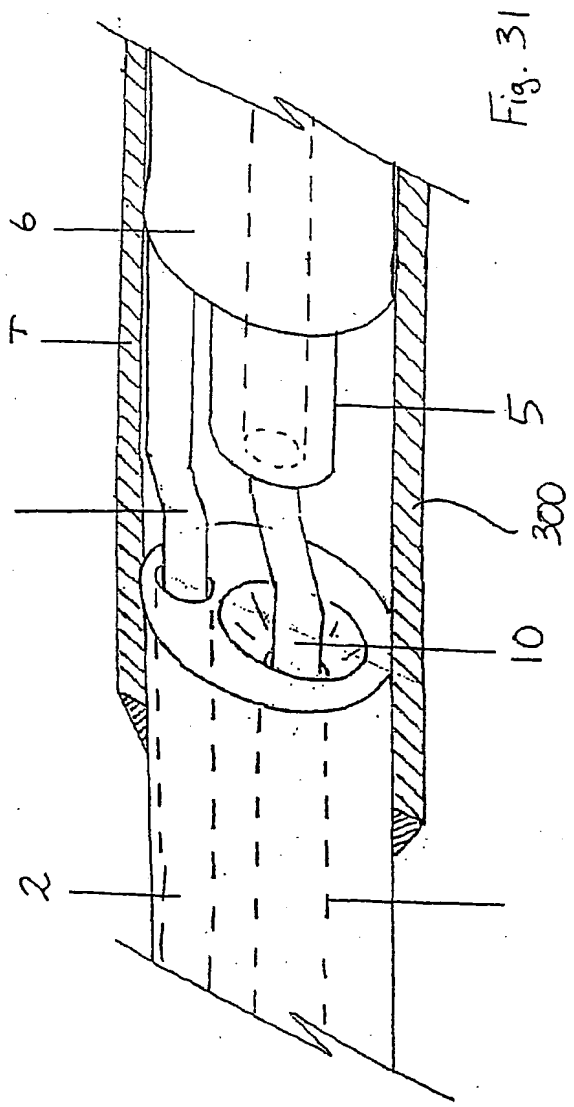


Fig. 31

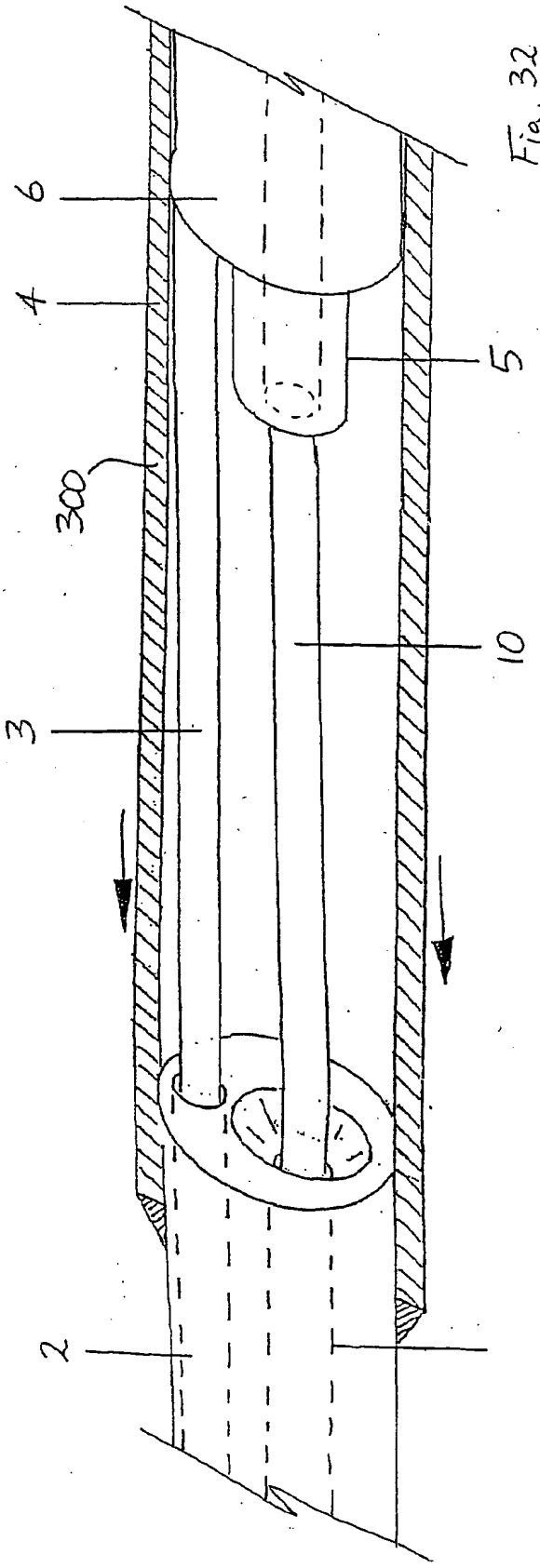


Fig. 32

PATENT COOPERATION TREATY

PCT

DECLARATION OF NON-ESTABLISHMENT OF INTERNATIONAL SEARCH REPORT

(PCT Article 17(2)(a), Rules 13ter.1(c) and Rule 39)

Applicant's or agent's file reference	IMPORTANT DECLARATION	Date of mailing *(day/month/year)*
SALV44/C/WO		05/11/2002
International application No.	International filing date *(day/month/year)*	(Earliest) Priority date *(day/month/year)*
PCT/IE 02/00090	27/06/2002	27/06/2001
International Patent Classification (IPC) or both national classification and IPC	A61F2	
Applicant		
SALVIAC LIMITED		

This International Searching Authority hereby declares, according to Article 17(2)(a), that **no international search report will be established** on the international application for the reasons indicated below

1. ☐ The subject matter of the international application relates to:
   - a. ☐ scientific theories.
   - b. ☐ mathematical theories
   - c. ☐ plant varieties.
   - d. ☐ animal varieties.
   - e. ☐ essentially biological processes for the production of plants and animals, other than microbiological processes and the products of such processes.
   - f. ☐ schemes, rules or methods of doing business.
   - g. ☐ schemes, rules or methods of performing purely mental acts.
   - h. ☐ schemes, rules or methods of playing games.
   - i. ☐ methods for treatment of the human body by surgery or therapy.
   - j. ☐ methods for treatment of the animal body by surgery or therapy.
   - k. ☐ diagnostic methods practised on the human or animal body.
   - l. ☐ mere presentations of information.
   - m. ☐ computer programs for which this International Searching Authority is not equipped to search prior art.

2. ☒ The failure of the following parts of the international application to comply with prescribed requirements prevents a meaningful search from being carried out:
   ☐ the description ☒ the claims ☐ the drawings

3. ☐ The failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions prevents a meaningful search from being carried out:
   - ☐ the written form has not been furnished or does not comply with the standard.
   - ☐ the computer readable form has not been furnished or does not comply with the standard.

4. Further comments: SEE ADDITIONAL SHEET

Name and mailing address of the International Searching Authority	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Sylvie Fernandez

Form PCT/ISA/203 (July 1998)

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 203

A meaningful search is not possible on the basis of all claims for the following reasons :

Claim 93, see Rule 6.2 (a) PCT.

The remaining 92 apparatus claims include 4 claims (claims 1, 66, 79, and 86) presented as independent claims, differing from one another by their technical content and / or the wording used to define such technical content.

The large number and also the wording of the apparatus claims presently on file renders it difficult, if not impossible, to determine the matter for which protection is sought. As a result the present application fails to comply with the clarity and / or conciseness requirements of Article 6 PCT (see also Rule 6.1 (a) PCT) to the extent that a meaningful search is impossible. Moreover, the requirements of Rule 6.4 PCT on the issue of multiple dependency of claims is also not complied with. Consequently, no search report can be established for the present application.

Although no formal objection concerning lack of unity has been made at this stage because of the above clarity and conciseness objection, it could also appear that several of the independent and also dependent claims define inventions which are not so linked as to form a single inventive concept, see Rule 13 PCT.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.5), should the problems which led to the Article 17(2) declaration be overcome.